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Ethylene Dibromide (EDB). Scientific Support and Decision Document for Grain and Grain Milling Fumigation Uses

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This Position Document addresses the risks and benefits of pesticide products containing the subject active ingredient. The Agency has determined that the use of products containing the subject active ingredient may meet or exceed a risk criterion described in 40 CFR Part 154. Potential hazards will be examined further to determine the nature and extent of the risk, and considering the benefits of the subject active ingredient, whether such risks cause unreasonable adverse effects on the environment.

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ETHYLENE DIBROMIDE (EDB)

Scientific Support and Decision Document for Grain and Grain Milling Fumigation Uses

OFFICE OF PESTICIDE PROGRAMS

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEBRUARY 8, 1984

EXECUTIVE SUMMARY

The Agency has determined that further Federal regulatory actions for pesticide uses of ethylene dibromide (EDB) are necessary to reduce the risks to human health. These actions include:

- immediate emergency suspension of all uses of EDB to fumigate stored grains and grain milling equipment;
- guidelines for maximum permissible levels of EDB in raw grains and consumer products made from grains;
- initiation of the rulemaking process to revoke the exemption from the tolerance requirements for EDB on grain products which is currently applicable; and
- establishment of appropriate federally enforceable maximum residue levels for EDB.

EDB exposure can pose risks to human health which include cancer, reproductive disorders and heritable genetic damage. Consequently, residues of EDB occurring in consumer products raise public health concerns. The actions the Agency is taking will reasonably reduce the present risks to human health from the uses of EDB to fumigate stored grains and to fumigate grain-milling equipment.

In September 1983 EPA announced a series of regulatory decisions for each of the pesticide uses of EDB. The Agency issued a Notice of Intent to Cancel registrations for the uses of EDB to fumigate grains and milling equipment. Pursuant to §6(b) of FIFRA, the cancellation of pesticide products which are the subject of a Notice of Intent to Cancel does not become effective when adversely affected persons file a request for a hearing for particular registrations and uses. Hearing requests were submitted. Subsequently two hearing requests have been withdrawn.

As a result of these challenges, the sale and distribution of several EDB-containing pesticides for use on stored grain and grain-milling equipment have continued to be legal under FIFRA. Historically, adjudicatory cancellation hearings have lasted about two years and may extend for longer periods. The Agency has concluded that this extended period of time is unacceptable in light of the additional risks to human health which would be expected to result as use of EDB continues. In its 1983 decision, the Agency stated that it would consider emergency suspension of the grain registrations of EDB if additional monitoring data confirmed widespread dietary residues in consumer grain products.

Recent results from numerous testing programs of consumer products confirm that there are residues of EDB in the nation's grain-based food supplies. EPA's monitoring efforts were aided by collaborative efforts by the Food and Drug Administration and the United States Department of Agriculture. Several states have supplied the results of significant numbers of samples of grain products analyzed for EDB. In addition, the American Bakers Association and the Grocery Manufacturer's Association and certain of its member companies have conducted extensive EDB analyses and submitted those results to EPA. The Agency has evaluated the results which have been provided by these public and private organizations, and s concluded that it would be appropriate to recommend EDB residue guidelines below which grain products should pose no extraordinary risks to public health. These recommendations are being made available to the public as well as to state governments and to the various sectors of the grain products industry. The Agency will initiate the rulemaking process necessary to revoke the current exemption of grain products containing EDB from the tolerance requirements of the Federal Food, Drug, and Cosmetic Act, and will seek the establishment of federally enforceable maximum residue levels.

The Agency has further concluded that the uses of EDB to fumigate grains and milling equipment are responsible for residues of EDB in the nation's grain-based foods and such use must be stopped immediately to eliminate continued contamination of grain-based consumer products.

The Agency has evaluated the economic impact of these actions and recommendations and has determined that there could be some economic disruptions, but that they are not unreasonable in light of the reduction in the hazards to human health which are expected to result.

This document summarizes the Agency Staff evaluation of exposure, risk and economic consequences of implementing alternative maximum permissible residue levels of EDB in grain and grain products and, at the same time, placing an immediate emergency suspension upon further use of EDB for fumigation of grain and grain milling equipment. The consequences of a number of optional levels of maxium permissible EDB residues were evaluated, for raw grain, cooked/ready-to-eat grain products and uncooked grain products. The results of the analysis are summarized in Table 1, including the option selected, which was to recommend against human consumption of products with EDB residues above 30 ppb (parts per billion)

Table 1. Human Health Risks and Economic Impacts of Alternative Maximum Permissible Residue Levels for EDB in Grain Products: Ready-to-Eat; Prepared/Uncooked and Raw Grain

Permissible Level		Exposure (Estimated Actual Intake)		Cancer Risk c/ (2 to 3-Years Exposure) d/		Economic Impacts					
						Ready-To-Eat		Prepared/Uncooked		Raw Grain	
No.	PPB a/	PPB in Grain Diet	Mg/Kg/Day Child/Adult	Child 1 (yr.)	Adults (30 yr.)	Percent Above Level (pct)	Value Above Level (mil.)	Percent Above Level (pct)	Value Above Level (mil.)	Percent Above Level (pct)	Value Above Level (mil.)
1	No Residue Limit	2.9	1.3x10^{-5}/ 6x10^{-6}	10-5 to 10-4	10-6 to 10-5	N/A	$ N/A	N/A	$ N/A	N/A	$ N/A
2	50/250/ 5,000	2.1	9x10^{-6}/ 4x10^{-6}	10-6 to 10-4	10-6	0.1	1	1.2	22	0.2	26
3	30/150/ 3,000	1.8	8x10^{-6}/ 3x10^{-6}	10-6 to 10-4	10-7 to 10-6	0.9	9	1.9	36	0.2	26
4	30/150/ 1,000	1.8	8x10^{-6}/ 3x10^{-6}	10-6 to 10-4	10-7 to 10-6	0.9	9	1.9	36	0.6	73
5	30/150/900	1.8	8x10^{-6}/ 3x10^{-6}	10-6 to 10-4	10-7 to 10-6	0.9	9	1.9	36	0.7	97
6	20/100 2,000	1.6	7x10^{-6}/ 3x10^{-6}	10-6 to 10-4	10-7 to 10-6	1.5	15	2.9	54	0.2	26
7	10/50/ 1,000	1.1	5x10^{-6}/ 2x10^{-6}	10-6 to 10-5	10-7 to 10-6	6.1	60	6.2	116	0.6	73
8	5/25/500	0.8	3x10^{-6}/ 2x10^{-6}	10-6 to 10-5	10-7 to 10-6	8.7	85	11.0	206	1.4	193
9	1/5/100	0.5	2x10^{-6}/ 9x10^{-7}	10-6 to 10-5	10-7	19.2	1.88	29.1	544	6.3	858
10 b/	Sliding scale	1.2	5x10^{-6}/ 2x10^{-6}	10-6 to 10-4	10-7 to 10-6	1.5	15	2.9	54	0.2/0.6	13/86

a/ Permissible residue levels listed are for ready-to-eat consumer products, milled products and raw grain respectively. Parallel levels assume a 5-fold increase from the finished product to the uncooked product and a 20-fold increase from uncooked product to grain (with the exception of #4&#5, which assume a 6-7-fold increase from uncooked product to grain).
b/ Residue level 10 assumes 6 months enforcement at 20/100/2,000 followed by permanent enforcement of 10/50/1,000 ppb.
c/ Range in cancer risk using dietary cancer models presented in the PD 2/3 and PD 4.
d/ A constant exposure was assumed for calculation purposes. Exposure is predicted to decline after the suspension is in effect.

Source: See Tables VI-1, VIII-8, 9, 15 and 18.

in ready-to-eat products, 150 ppb in prepared/uncooked grain products and 900 ppb in raw grain. Enforcement of this option would mean that generally 1 to 2 percent of grain and related products would exceed these levels, with such stocks having a value of nearly $150 million. Economic impacts would be most significant in the immediate future, and would dissipate as EDB-contaminated stocks of grain and related products are eliminated from the food system in a period to three to five years.

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TABLE OF CONTENTS

Executive Summary

Page

I. Introduction.. 1

II. Background.. 4

III. Use and Usage.. 7

IV. Residue Data.. 10

V. Consumption Pattern and Dietary Burdens.............. 33

VI. Cancer Risks.. 51

VII. Toxicity of Likely Chemical Alternatives............. 57

VIII. Economic Impacts.. 63

I. Introduction

On September 28, 1983, EPA issued a Notice of Intent to Cancel registrations for the pesticidal uses of EDB which were determined to be responsible for residues occurring in consumer grain products. These uses include spot fumigation of grain milling equipment, and fumigation of stored grains. These cancellation notices were the result of an evaluation of the long-term risks to public health and the economic consequences of cancellation.

FIFRA §6(b) provides that adversely affected parties may challenge these cancellation actions through requests for adjudicatory hearings. For the specific products for which hearings have been requested, registrations remain unaffected by the cancellation actions until the cancellation proceeding is concluded for these products. The products subject to the cancellation hearing, therefore, can continue to be sold, distributed, and used until the hearings end and the Agency announces its final regulatory decision. Historically, adjudicatory hearings average 2 to 3 years or more.

In announcing its decisions to cancel registrations of EDB for fumigation of stored grain and milling machinery, the Agency stated that further federal action might be necessary if the cancellation was delayed by a hearing request and additional residue data increased the Agency's concern for human health risks. At the time the notice of cancellation was issued, there was very little data on the actual residues of EDB occurring in grain-based consumer products. The cancellation action was instead based primarily on residue levels which the Agency predicted would result from these two uses of EDB.

The information now available on residues occurring in consumer products is greatly expanded, and clearly demonstrates the need for additional federal actions. These actions include:

1. Emergency suspension of the uses of EDB for spot fumigation of milling equipment and fumigation of stored grain;
2. Revocation of the exemption from tolerances of residues of EDB in fumigated grains, and;
3. Steps to establish appropriate federally enforceable maximum permissible residue levels.

Claims that this contamination is the result of other sources of EDB such as gasoline or a naturally occurring source of EDB have been rejected. The Agency knows of no scientifically sound studies which can reasonably explain that these or other possible sources are responsible for this extensive contamination of the nation's food supply.

The comprehensive scientific and technical analyses and extensive data discussed in this document and the PD 2/3 and PD 4 provide the basis for the Agency's decision to emergency suspend the stored grain and milling uses of EDB. Additional analyses provided are the basis for the Agency's recommendation of the maximum permissible residue levels during the period of time required for treated grains to clear the food supply. Included in this document are:

1. a survey of the extent of use of EDB to fumigate grains and to fumigate grain milling equipment;
2. a detailed evaluation of all available data on residues of EDB occurring in grains, and grain-based consumer products before and after cooking;
3. an evaluation of dietary consumption patterns to determine "typical" consumption of grain-based products and levels of intake for subgroups of the population with high grain consumption;
4. dietary burdens or residue consumption levels for dietary patterns developed in 3 above, both for best judgement estimates of EDB contamination levels, and also for hypothetical maxmimum permitted residue standards;
5. estimated human health risks for dietary burden levels developed in 4 above;
6. economic impacts expected to occur for hypothetical maximum permitted residue levels and impacts of the use of alternative fumigation methods;
7. economic impacts of immediate suspension of the grain and milling registrations during the next six months and two years; and
8. summaries of readily available information on the toxicity of alternative chemicals.

This document reflects the information upon which the Adminsitrator's February 3, 1984 Suspension Order and recommended maximum residue levels were based. A final February 3, 1984 version of this document has been maintained by EPA. This February, 1984 document reflects additional explanatory material and some additional analyses, but does not materially differ from the February 3 document.

II. Background

On September 28, 1983, the Administrator signed a Notice of Intent to Cancel the registrations of pesticide products containing EDB and labeled for use as a fumigant of grain stored in bulk, and as a spot treatment of grain milling equipment. The cancellations of 16 registrations for the stored grain uses, and 4 registrations for spot treatment of milling equipment did not go into effect because requests for a hearing on the proposed cancellation action were filed by 9 parties. One registrant has since withdrawn and voluntarily cancelled 2 registrations for the stored grain use. A second registrant has voluntarily cancelled a registration for grain fumigation and spot treatment of milling equipment.

The Agency's notice of cancellation concluded an extensive analysis of the risks and benefits of the use of EDB as a pesticide under the Agency's Rebuttable Presumption Against Registration (RPAR) process.

The Environmental Protection Agency issued a Notice of Rebuttable Presumption Against Registration and a Position Document 1 (EDB PD 1) concerning the pesticide products containing ethylene dibromide (EDB) in the FEDERAL REGISTER of December 14, 1977 (42 FR 63134). The Agency took this action in response to test results which showed that EDB induced cancer, mutations, and adverse reproductive effects in test animals. The EDB PD 1 discussed the relevant test data and the Agency's concerns with the continued use of EDB as a pesticide. The document also solicited public comments and additional data.

Comments and data in response to the EDB PD 1 were submitted to the Agency by registrants, user groups, and other members of the public. The Agency carefully evaluated the comments and additional data which were submitted, and in the FEDERAL REGISTER of December 10, 1980 (45 FR 81516), the Agency announced the preliminary notice of determination for EDB and the availability of the EDB PD 2/3.

In the EDB PD 2/3, the Agency concluded that EDB poses a significant risk of oncogenic, mutagenic, and adverse reproductive effects in the human population. In addition, the EDB PD 2/3 contained analyses of the risks and benefits of continuing the various uses of EDB and presented the Agency's proposed regulatory decisions.

The EDB PD 2/3 was submitted to the Scientific Advisory Panel (SAP) and the U.S. Department of Agriculture (USDA) for review and comment. The SAP held public hearings concerning the EDB PD 2/3 on March 25-26, 1981, and heard presentations by the Agency, registrants and other interested members of the public. Both SAP and USDA submitted comments on the EDB PD 2/3 to EPA on April 22, 1981 and April 8, 1981, respectively.

The Agency again received numerous comments from registrants, user groups, and other members of the public. All comments were reviewed and evaluated by EPA in arriving at the final regulatory positions concerning the uses of EDB as a pesticide. Comments which included significant information were analyzed and discussed in the EDB PD 4. The Notice of Cancellation was published in the FEDERAL REGISTER on October 11, 1983 (48 FR 42668).

Since the Notice of Cancellation was issued, an administrative hearing has commenced to consider, among other things, the cancellation of pesticide products containing EDB for use as a fumigant of stored grain and a spot treatment for milling equipment. The first prehearing conference was held on December 1, 1983. A second prehearing conference is scheduled to be held on March 5, 1983. The date of commencement of the testimony in the hearing is not yet set, but it is estimated that least 2 years may elapse before a cancellation order could be issued at the close of the hearing.

III. EDB Usage Estimates

An estimated 452,000 gallons of formulated products containing 471,000 pounds of EDB active ingredient are used annually for insect control in grain stored in bulk and flour milling machinery (Table III-1).

For grain storage uses, 425,000 gallons of formulated products were applied to an estimated 202 million bushels of grain in 1983. Usage on wheat is believed to comprise about 75% of annual usage; corn 10%; oats, rye, rice, and barley 10%, and grain sorghum 5%. In total, the estimated bushels treated comprise about 2.4 percent of 1983 production of these commodities, and 1.4 percent of the total supply of these commodities. It should be noted that these estimates do not include mixing or blending of grain as it moves through commerce.

The estimated 159.4 million bushels of wheat treated in 1983, represent about 6.6 percent of the 1983 production and about 4 percent of total wheat supply for 1983 (beginning stocks, plus production and imports). Corn is the other major grain crop treated with EDB; with about 10% of EDB usage in 1983 on about 14.2 million bushels. Corn treated comprises about 0.3 percent of 1983 production, and about 0.2 percent of 1983 supply. Stored grain treatments with EDB are most common in the late summer and early fall. EDB usage during the year on stored grain is believed to be distributed on a quarterly basis as follows: 10% First Quarter; 15% Second Quarter; 25% Third Quarter; and 50% Fourth Quarter.

Table III-1. Estimated Annual Usage of Formulated EDB as a Fumigant of Grain Stored in Bulk and for Spot-Treatment of Flour Milling Equipment

Item	Grain Storage	Flour Milling a/	Total
Gallons of formulated product applied:	425,000	27,277	452,277
Pounds A.I. Applied:	170,400	300,600	471,000
Units treated:	202 million bu.	243 mills	

a/ Usage of EDB by the majority of flour milling firms was apparently voluntarily halted in August/September 1983. Estimates are for a typical recent year of usage.

Sources: Centaur, 1983; Douglas Chemical Co., 1984; and EPA Estimates.

States leading in EDB usage to fumigate stored grain include Minnesota, North Dakota, Iowa, South Dakota, Nebraska, Oregon and Indiana.

EDB usage to spot treat flour milling machinery was apparently voluntarily discontinued in August and September, 1983, by the major producers in the milling industry. Prior to that time, typical annual usage was about 300,600 lbs. active ingredient. The majority (75-80%) of the industry employed EDB to combat insect infestations in milling machinery. The frequency of usage varies widely but averaged 10-11 annual treatments in 231 to 243 flour mills during recent years. Approximately 10.5 gallons are used (range 2-45 gallons) per mill fumigation.

IV. Residues of EDB in Grain and Grain Products

This section contains a summary and discussion of the available data on EDB residues in grain and grain products throughout the United States.

A. Raw Grain

The available data indicate a large variation in the EDB residues in fumigated grain. This is due to several variables including the use patterns, temperature, amount of aeration, and time in storage. Length of time in storage appears to be the predominant factor in determining the level of EDB in treated grains.

Table IV-1 contains estimates of the maximum likely EDB levels at various post-fumigation intervals.

Table IV-1. Estimated EDB residue (ppb) in fumigated grain at various intervals post-treatment

Grain	Maximum Application Rate/1000 bu	Calculated Initial Residues	Post-Fumigation Time 1 wk.	2 wk.	30 days	60 days	90 days
		-ppb-					
Barley, Oats, Popcorn, Rice, Rye and Wheat	7.2 lbs.	120,000	60,000	47,000	27,000	10,000	3,400
Corn	9.0 lbs.	140,000	75,000	58,000	33,000	11,000	4,200
Sorghum	11.0 lbs.	183,000	92,000	72,000	41,000	14,000	5,100

Source: Worthington, 1978

The calculated initial residues in Table IV-1 are derived assuming that the maximum registered application rates are used. If lower application rates are used, the calculated values would be reduced proportionately. Moreover, these calculations assume there is no mixing of treated grains with untreated grains and therefore no reduction of residues through dilution.

A large volume of monitoring data for grains has been received by the Agency. These data are summarized in Table IV-2. The data indicate a wide variation in residue levels, which would be expected from the use of EDB on a small percentage of the grain (5%). Surprisingly, however, the extent of EDB contamination of raw grain is much greater than 5%. About 60% of all tested raw grain samples contained detectable residues of EDB. This is likely attributable to mixing during storage and transit of treated grain with grain which has not been treated or that the estimate of the percent of grain treated was wrong.

The monitoring data described in the previous paragraph were combined to give an estimate of the distribution of EDB in raw grains. The combined results of all of these studies are presented in Table IV-3. In this table, the total number of samples, the average residue and the standard deviation of the average residue are given in the last three columns entitled "no regulatory restriction level." Values are given for wheat, corn and other grains (rice, barley, oats, rye and sorghum). Table IV-3 also includes the effect of setting various maximum permissible residue levels. This calculation assumes that enforcement results in removal from commerce of 100% of all grains containing residues above the maximum

Table IV-2. Residue Data for EDB in Raw Grain

Study	Reference	Grain	Number of Samples	Average Residue (ppb)	Standard Deviation
FDA-1	IV 3	Wheat	31	33	85
		Other	6	2000	4000
NC	IV 9	Wheat	2	27	—
		Corn	3	N.D.	—
		Other	3	N.D.	—
USDA-1	IV 14	Wheat	10	4.9	7
		Corn	10	0.9	0.5
		Other	10	2.1	2.4
USDA-2	IV 12	Wheat	197	36	61
		Corn	202	5.6	26
		Other	1	N.D.	—
GMA	IV 1, 2	Wheat	622	43	150
		Corn	69	220	1200
		Other	90	5.7	20
Texas	IV 5	Corn	6	1.4	1.6
		Other	2	N.D.	—

Table IV-3 Impact of Proposed Maximum Permissible Residue Levels (MPL) on Average (mean) EDB Residues in Raw Grains

	100		500		900/1000		2000		3000		5000		No Restriction Level		
Guideline Level in ppb Product	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	All Samples	Average Residue	Standard Deviation
Wheat	783 (90.8)	12	850 (98.6)	27	858 (99.5)	34	862 (100)	40	862 (100)	40	862 (100)	40	862	40	130
Corn	279 (96.2)	5	286 (98.6)	13	289 (99.7)	21	289 (99.7)	21	289 (99.7)	21	290 (100)	21	290	56	590
Other	108 (96.4)	3.7	110 (98.2)	7.0	110 (98.2)	7.0	111 (99.1)	21	111 (99.1)	21	111 (99.1)	21	112	110	950

permissible residue level. The extent of reduction will depend on the effectiveness of enforcement. Thus, the averages given in Table IV-3 should be taken as the maximum possible reduction in average residues, which may not be achieved in reality.

B. Effect of Milling on Residues in Grain

Residues in processed grain products can result from residues in the bulk grain and also from residues resulting from spot fumigation of mills and milling equipment. While the milling process may reduce levels (i.e. produce lower levels in flour than in bulk treated grain), spot fumigation of mills will contribute additional residues during milling.

1. Effect of Milling on Residues in Grain

In a controlled study by Wit et. al. (IV-16) (1969), treated wheat containing an average of 9,500 ppb EDB was milled. After milling, residues in the flour averaged 3,000 ppb (68% reduction) and residues in shorts/bran averaged 14,600 ppb (a concentration factor of 1.5x). In a similar experiment by Berk (IV-15), treated wheat grain containing an average of 376 ppb EDB was milled. After milling, residues in the flour averaged 98 ppb (74%, reduction), residues in the shorts/bran averaged 106 ppb (0.3x) and residues in middlings averaged 78 ppb (0.2x).

Recently (1983), in a controlled experiment by the USDA (IV-18), fumigated wheat grain containing an average of 3,690 ppb EDB was milled. After milling the average residues in the flour was 520 ppb (after subtracting contribution from spot treatment), a reduction of 86%.

In a study carried out by the Grocery Manufacturers of America (IV-1), fumigated wheat containing 17,816 ppb EDB was milled. After milling, residues in the flour were an average of 967 ppb (95% reduction).

It is concluded from these studies that residues in the treated grain are retained in the processed fractions. Residues in the flour are generally lower than the residues in the grain. EDB residues may concentrate in selected milled fractions other than flour.

The studies reported above are all controlled experiments and are presumed to be broadly indicative of the changes in residue levels that would occur during commercial milling. No data on the effect of processing on residues in milled products are available for grains other than wheat.

-- Contribution from Spot Fumigation

In a study conducted by Litton Bionetics (IV-17), it was shown that spot fumigation with EDB resulted in residues in flour that generally follow a log-linear curve. Initial EDB residues in the wheat-flour in the first half hour after start-up of the milling process was determined at 2,750 ppb. This level declined to 900, 170 and 30 ppb after 1.5 hrs., 3 hrs., and 1 week, respectively. A time-weighted average contribution to the wheat flour from spot treatment was estimated in the Agency's PD-4 (September 27, 1983) at 34-68 ppb (based on a 4-week time weighted average). Actual levels in flour ranged from 54 to 2,750 ppb, some of which may have been attributable to bulk grain fumigation.

In a controlled study conducted by the USDA (IV-18), it was shown that contribution to the initial wheat flour from spot fumigation averaged 240 ppb. Because the wheat was treated and processed in a laboratory study, contribution from spot treatment in this test may not be representative of grain in commerce that received multiple applications. It is also noted that this study was run for only a short time after fumigation, commercial mills are normally treated only once every 2-4 weeks, and residues in flour fall to lower levels with time. Thus the 240 ppb average residue observed in this study is higher than the average residue expected in a commercial mill.

C. Intermediate (Uncooked Grain Products)

Monitoring data for uncooked grain products were reported by the Grocery Manufacturers of America, Inc., FDA, Midwest Research Institute, the States of Florida, Georgia, North Carolina, California and Texas. The data for each of these studies are summarized in Table IV-4. The data on uncooked grain products were analyzed as described previously for the raw grains. The results of this analysis are presented in Table IV-5. This table

Table IV-4. Residue Data for EDB in Uncooked Grain Products

Study	Reference	Grain	Number of Sample	Average Residue (ppb)	Standard Deviation
FDA-1	IV 3	Wheat	13	4.0	4
		Other	3	1.2	--
FDA-2	IV 3	Wheat	10	1.8	2.8
Georgia	IV 8	Wheat	4	3.7	--
		Corn	9	3.2	5.5
		Other	1	0.75	--
Florida	IV 6	Wheat	39	2.9	7.4
		Corn	107	19	86
Texas	IV 5	Wheat	40	21	20
		Corn	50	8.5	26
		Other	32	5.4	23
N.C.	IV 9	Wheat	51	19	38
		Corn	43	4.3	7.4
		Other	1	2.3	--
GMA	IV 1, IV 2	Wheat	473	15	46
		Corn	74	140	250
		Other	9	0.87	0.35
MRI	IV 10	Wheat	8	22	37
		Corn	20	16	25

Table IV-5. Effect of Proposed Maximum Permissible Residue Levels MPL on Average (mean) EDB Residues in Uncooked Products

Guideline Level in ppb	5		25		50		100		150		250		No Restriction Level		
Product	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	All Samples	Average Residue	Standard Deviation
Wheat Uncooked Products	425 (66.6)	1.6	558 (87.5)	3.8	598 (93.7)	6.1	623 (97.6)	9.2	628 (98.4)	10.0	632 (99.1)	11.0	638	14.4	42
Corn-Uncooked Products	193 (63.7)	1.3	257 (84.8)	3.7	267 (88.1)	5.0	279 (92.1)	7.6	281 (92.7)	8.4	286 (94.4)	12.0	303	44.0	140
Other Grains-Uncooked Products	43 (93.5)	0.89	45 (97.8)	1.3	45 (97.8)	1.3	45 (97.8)	1.3	46 (100)	4.0	46 (100)	4.0	46	4.0	19

includes the total number of samples, the average residue and the effect of various maximum permissible residue levels on the average residues in wheat, corn and other grains. The data generated by Rains and Holder in 1980 (IV-19) on school lunch flour were not included in this data analysis. These results were significantly higher than the current monitoring data and thus are not considered reflective of current residue levels.

D. Cooking Studies

Several studies have been carried out to determine the extent of reduction of EDB residues upon cooking. In this section only data on the cooking of commercial products are included. Studies involving spiked products are not included.

In a study by the Midwest Research Institute (IV-10), 32 samples of corn meal, hushpuppy mix, instant and regular grits, cake mixes, pancake and cornbread mixes containing from <0.5-110 ppb EDB were prepared as ready-to-eat products, following the label instructions. Residues of EDB in the cooked products were reduced by 67-99% and ranged from ND (<0.75 ppb) to 36 ppb in the final duct.

In a study by FDA (IV-11), 7 samples of cornmeal, cornmeal mix, quick grits and hushpuppy mix obtained from Florida and containing from 1.9-586 ppb EDB were prepared as ready-to-eat products following standard recipes. Residues of EDB were reduced by 47-97% and ranged from <1 ppb-92 ppb in the ready-to-eat products.

In a study conducted by the Grocery Manufacturers of America, Inc. (IV-1), 95 samples of wheat flour, wheat germ, pasta, mixes, corn meal, hushpuppy and grits obtained from GMA member companies containing EDB residues from <1-990 ppb were prepared as ready-to-eat products. Residues of EDB were reduced by 50-99% and ranged from ND (<0.75 ppb)-32 ppb in the ready-to-eat products.

In another study by GMA (IV-1), 24 examples of wheat flour, mixes and pasta fortified with EDB containing from 9.8-674 ppb were prepared following the label instructions. Residues of EDB were reduced by 88-98% and ranged from ND-92 ppb in the ready-to-eat products.

In a study by the State of Florida (IV-6), 48 samples of wheat flour, cake mix, corn meal, hushpuppy, grits, and corn muffin obtained from local markets containing from <1-800 ppb, were prepared as ready-to-eat products following the label instructions. Resides of EDB were reduced by 79-100% and ranged from ND (<0.75 ppb)-52 ppb in the ready-to-eat products.

In general, the reduction of EDB residues upon cooking appears to be greater at higher contamination levels. The average reductions upon cooking for all reviewed studies was 82%. In calculating the dietary exposure, an 80% reduction upon cooking factor is used. The available data on reduction of residues on processing is summarized in Table IV-6.

Table IV-6. Data on the Effect of Cooking on EDB Residues*

Study	Reference	Number of Experiments	Average Reduction
Florida	IV 6	32	88.4%
FDA	IV 11	8	84.0%
GMA	IV 2	100	80.2%
MRI	IV 10	13	79.0%
			82.0% weighted average

*Not counting those experiments in which the uncooked product contained <3 ppb EDB.

E. Ready-to-Eat Grain Products

Monitoring data for ready-to-eat products derived from grains were reported by the Midwest Research Institute, and the States of Florida, Georgia, North Carolina, California, and Texas and the Grocery Manufacturers of America, Inc. The data from each of these studies are summarized in Table IV-7.

The data on ready-to-eat grain products was analyzed as described for raw grains. The results of this analysis are given in Table IV-8. This table shows the total number of samples analyzed, the average residue levels and the effects of various maximum permissible residue levels on the average residues found in ready-to-eat wheat, corn and other grain products.

The data on residues in uncooked and cooked grain products in Tables IV-5 and IV-8 were used to estimate the average residue level for EDB in ready-to-eat grain products. In this calculation the Agency assumed an 80% reduction of residue on cooking. Thus, the average residue levels shown in Table IV-5 for uncooked grain products were reduced by 80% and averaged with the residue data for cooked commodities given in Table IV-8. The average residue level was calculated by weighting the average residue by the number of cooked and uncooked samples. Samples with no detectable residues were treated as having 0.75 ppb. The Agency utilized the uncooked sample data in addition to the cooked sample data because of the much larger number of uncooked samples analyzed. The Agency did not use the data from Table IV-3 for raw grains because of the larger error involved in extrapolating from raw grains to cooked ready-to-eat residues. The results of the weighted average

Table IV-7. Residue Data for EDB in Cooked Grain Products

Study	Reference	Grain	Number of Sample	Average Residue (ppb)	Standard Deviation
FDA-2	IV 3	Wheat	10	N.D	—
		Other	12	N.D	—
Georgia	IV 8	Wheat	3	N.D.	—
		Corn	6	4.5	5.3
		Other	3	N.D.	—
Florida	IV 6	Wheat	2	N.D.	—
		Corn	29	4.7	10.0
		Other	9	N.D.	—
Texas	IV 5	Wheat	3	N.D.	—
		Corn	6	1.1	0.76
N.C.	IV 9	Wheat	5	7.7	9.5
GMA	IV 1, IV 2	Wheat	243	2.2	4.9
		Corn	31	2.9	4.5
		Other	65	0.84	0.41
MRI	IV 10	Wheat	6	6.8	14
		Corn	20	4.7	7.5

Table IV-8. **Effect of Proposed Maximum Permissible Residue Levels (MPL) on Average (mean) EDB Residues in Ready-to-Eat-Products**

	1		5		10		20		30		50		No Restriction Level		
Guideline Level in ppb Product	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	No. Samples below mpl No. (%)	Average Residue	No Samples below mpl No. (%)	Average Residue	No Samples below mpl No. (%)	Average Residue	All Samples	Average Residue	Standard Deviation
Wheat Ready-to-Eat Products	217 (79.8)	0.72	248 (91.2)	0.91	255 (93.8)	1.1	267 (98.2)	1.7	269 (98.9)	1.8	272 (100)	2.3	272	2.3	5.3
Corn-Ready-to-Eat Products	55 (64.0)	0.76	66 (76.7)	0.96	73 (84.0)	1.6	84 (97.7)	3.3	85 (98.8)	3.5	85 (98.8)	3.5	86	4.1	7.4
Other Grains-Ready-to- Eat	95 (95.0)	0.66	100 (100)	0.73	100 (100)	0.73	100 (100)	0.73	100 (100)	0.73	100 (100)	0.73	100	0.73	0.46

calculations are given in Table IV-10. The results given in Table IV-10 are skewed due to overrepresentation of some portions of the diet. The averages are based on the samples analyzed and not corrected for the percent of the diet of each product type.

F. Limitations of the Residue Data

While a large volume of residue data are available, there are several limitations that must be considered in evaluating these data. The maximum permissible residue levels discussed in this paper should be accepted with the caveats as discussed below.

The estimates are based mostly on residue data from monitoring studies and only a few controlled experiments. The data comes from a variety of sources which possibly followed different sampling and testing protocols.

In most of the submitted residue studies there is no significant information available concerning application rates; methods of application; whether bulk or spot fumigation was used; length of exposure, aeration intervals, temperatures during treatment and storage or the interval fr [illegible] treatment to sampling. Without treatment histories for the monitoring samples, the Agency cannot ensure that the maximum residue level that may result from the registered uses are found. On the other hand, some of the values reported in the monitoring studies may be the result of misuse and may, therefore, be higher than the maximum residue level that would likely result from the registered uses. Further, residue levels may vary seasonally due to temperature variations during treatment and shipping.

The following caveats are of somewhat lesser importance and are not expected to significantly affect the overall results. The available studies do not usually specify whether standardized sample collection procedures were followed; e.g., whether grain tiers were uses for taking core samples of commodities in bulk quantities; whether samples were composited by quartering; whether the quantity sampled was adequate; and whether the samples shipped and stored were frozen or in cold storage.

In general, various modifications of the Rains/Holder method (J.AOAC 64(5) 1252-54, 1981) were used to quantify the residue levels. For some of the data submitters, the analytical methodology used was not given. In only a few instances were the data cross-checked by analysis at different laboratories.

In no study is the sample representative of all products on the market. Indeed, some studies purposely chose samples that concentrated on products where high residues were expected; this practice extended to looking for particular lots. Many variables which are likely to be related to contamination are either unknown or known to be nonrepresentative of the U.S. as a whole. Some of these variables are:

The state data analyzed to date are primarily from Southern States and California. However, new data being submitted to the Agency by various states appears to be consistent with the data already analyzed. All data indicate that cake mix and corn products, especially hushpuppy mix, are often contaminated.

But many other products have never been sampled, an samples of other than wheat and corn products are very limited. Thus, an important source of exposure to EDB may have been overlooked. There is no way to ensure that all samples taken have been reported to the Agency.

The following limitations apply to the data on reduction of residue in processing. The data are not directly comparable because they come from different sources. Even within a single study, different facilities and procedures may have been used. In no study is the sample of cooked goods representative of dietary patterns. Because the reduction apparently increases with the initial residue, the selection of which products to cook can bias the results. Some studies cooked only high-residue products, increasing the reported reduction. Some studies may not be representative of consumer baking practices. The reduction in residue may depend on whether the product was baked, boiled, or fried; at what temperature; and for how long. These differences cannot be estimated with the available data. The observed reduction in residue levels is a combination of loss of EDB by volatilization, decomposition and dilution with uncontaminated ingredients. EDB residues below 1 ppb cannot be measured accurately, thus for the cooked samples in which cooking reduced residues below 1 ppb, the percentage reductions cannot be computed accurately. The Agency conservatively treated levels below 1 ppb as .75 ppb which should tend to underestimate the actual reduction in cooking. However, all monitoring data and data on cooking are subject to the limitations discussed above. The data being submitted to the Agency on a daily basis by various states support the residue estimates discussed in this section.

G. Residues in Baby Food

Table IV-9 summarizes the available data on baby foods. Only two of 89 samples contained detectable residues of EDB and these samples were <1.5 ppb.

H. Residues in Meat, Milk, Poultry and Eggs

No controlled livestock feeding studies have been conducted for EDB and the Agency is unable to conclusively evaluate the potential for transfer of residues from grain-based feed to meat and milk. It is reassuring, however, that the monitoring to date has not shown significant residues in any of the meat, milk, poultry and eggs tested to date.

I. Additional Data

This report includes all monitoring data available to the Agency during preparation of this report. Additional data is being received daily and will be included in all future analyses. The Federal agencies, State agencies, and trade associations response to the Administrator's letter of January 13, 1984 requesting data on EDB shows an outstanding level of cooperation. Those data are being scanned as received to determine if patterns contrary to those established by the statistically analyzed data are observed. In general, the new data have served to confirm previous analyses.

Table IV-9. Baby Foods - Data on EDB up to 1/28/84

Source	Type	# of Samples	# (+)	Range (ppb)	Average Residues (ppb)
FDA	infant cereal	12	0		<1
GMA (IV-1)	wheat cereal	12	0		<1
GMA (IV-2)	wheat cereal	16	1	<1-1.3	<1
	rice cereal	15	1	<1-1.5	<1
	oat meal	1	0		<1
Florida	wheat cereal	7	0		<1
	corn cereal	5	0		<1
Texas (IV-5)	barley cereal	1	0		<1
	oat cereal	1	0		<1
	multigrain cereal	2	0		<1
Georgia (IV-8)	Rice cereal	2	0		<1
	multigrain cereal	1	0		<1
North Carolina (IV-9)	wheat cereal	4	0		<1
	rice cereal	1	0		<1
	oat cereal	1	0		<1
FDA (IV-3)	wheat cereal	6	0		<1
Total		86	2	<1-1.5	<1

Table IV-10. Effect of Proposed Maximum Permissible Residue Levels (MPL) on Weighted Average (mean) Residue Levels of Ready to Eat Products (Table I) and Uncooked Products

Proposed MPL Product	1	5	10	20	30	50	No Regulatory Restriction
Wheat	N.D.	0.81	1.2	1.8	2.0	2.2	2.7
Corn	N.D.	0.79	1.1	1.9	2.1	2.6	7.8
Other Grains	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.

a/*After adjusting for 80% reduction of residues by cooking.
N.D. - non-detectable (≤ 0.75 ppm).

J. References

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V. Dietary Patterns/Dietary Burdens

A. Dietary Patterns

The food consumption estimates were prepared using The EPA Tolerance Assessment System (Chaisson et al., 1984) and dietary estimates derived from the most recent nationwide survey of individuals. This survey of three day dietary records for 30,770 individuals was conducted by the U.S. Department of Agriculture in 1977-78. The USDA survey design is summarized in section V-D-1. The methods which were used to adapt the USDA data to a form comparable to the residue data described in chapter IV are summarized in section V-D-2.

Briefly, the data file used to estimate EDB dietary burdens contains the quantity and form of each Raw Agricultural Commodity (RAC) eaten per unit of body weight/day. The record is on an individual basis, and is accompanied by demographic and socioeconomic information for that individual (age, sex, ethnic origin, region of the country, season surveyed, pregnant or nursing, etc). Therefore, subgroups of the U.S. population can be analyzed for differences in their dietary profiles, allowing the calculation of differences in dietary burdens of EDB. Subgroups analyzed for exposure to EDB were the U.S. population (48 states, all seasons), 4 regions (northeast, north central, southern, and western), 4 seasons (spring, summer, fall and winter), ethnic (hispanics, non-hispanic whites, non-hispanic blacks, and-other), infants (nursing and non-nursing), children (1-6 and 7-12 yrs), teenagers 13-19 (male & female), 20+ (male and female), and females who were pregnant or nursing.

Two analytical procedures are available for estimating exposure to EDB. The first procedure uses values for mean consumption of products to estimate the average exposure for the U.S. population and for subgroups of the population. These exposure estimates were then used to estimate risks.

The second procedure generates a set of of exposure estimates - one for each respondent in the USDA survey - that is, the estimated exposure to EDB for that day for that individual. Individual exposures are then analyzed by subgroup to estimate the mean (weighted) exposure and to estimate the percentage of the subgroup who exceeded predetermined daily intake levels. This procedure generates a curve which describes the distribution of exposure over the population, and allows other regulatory options to be compared for their impact upon exposure.

This approach provides a mechanism to examine differences in eating patterns among subgroups of the U.S. population.

Subpopulations were examined for differences in either quantities or patterns of grain consumption. Consumption of the three major grains is summarized in Table V-1 for subgroups who consumed more grains than the national average or who had different patterns of consumption. Infants and children under the age of 12 consume almost twice the national average grain consumption - when consumption is expressed per unit body weight. Certain ethnic groups also consume more grains than the national average. The contribution of each grain to the diet varies for different subgroups. Grain consumed by the U.S. population is 74% wheat, 10% corn, 8% rice and 8% "other" grains. Hispanics have different patterns, reporting 56% of their grain consumed as wheat, 17% as rice and 21% as corn. Non-nursing infants (less than 1 yr) have very different patterns with grain consumption distributed as 4% barley, 8% corn, 21% oats, 37% milled rice and 29% wheat. Patterns for other subgroups are summarized in Table V-1.

B. Dietary Burdens

Exposure is a function of the residue level in each grain at the time it is consumed and the quantity of that food consumed. Dietary burden is the sum of the EDB consumed in each grain. Using the second procedure, described above, it is possible to analyze each individual's dietary burden. For example, non-nursing infants consume more rice than other grains. Therefore, the fact that monitoring data has found lower levels of EDB in rice than in other grains will have a greater impact on the dietary burden for non-nursing infants than it will for the U.S. population. This is illustrated by two hypothetical examples: 10 ppb on all grains

Table V-1. Patterns of Grain Consumption

SUBGROUP	WHEAT	RICE	CORN	OTHER	ALL GRAINS
	g food/kg body weight/day(% of grain consumption)				
US. population (48 states)	1.4(73)	0.16(8)	0.19(10)	0.15(8)	1.9
Ethnic groups					
Hispanics	1.35(56)	0.41(17)	0.49(21)	0.14(6)	2.4
Non-hispanic whites	1.44(78)	0.11(6)	0.14(8)	0.16(9)	1.9
Non-hispanic blacks	1.26(65)	0.25(13)	0.35(18)	0.09(5)	2.0
Other	1.34(55)	0.78(32)	0.18(7)	0.15(6)	2.5
Infants & Children					
Non-nursing infants	1.03(29)	1.32(37) a/	0.29(8)	0.90(25)	3.5
1-6 yr.	b/	b/	b/	b/	4.3
7-12 yr	b/	b/	b/	b/	3.0
Regions					
Northeast	1.47(74)	0.20(10)	0.09(5)	0.19(10)	2.0
North Central	1.45(76)	0.11(6)	0.14(7)	0.16(9)	1.9
Southern	1.35(71)	0.16(8)	0.26(13)	0.11(6)	1.9
Western	1.36(72)	0.17(9)	0.23(12)	0.17(9)	1.9

a/ All milled rice.
b/ Not presently available

except 1 ppb on rice is:

	DIETARY BURDEN	
Residue levels (ppb EDB)	**U.S. population**	**Non-nursing infants**
	mg EDB/KG body weight/day	
10 ppb, all grains 0 ppb other foods	1.9×10^{-5}	3.5×10^{-5}
10 ppb all grains except 1 ppb rice, 0 ppb other foods	1.8×10^{-5}	1.3×10^{-5}

The second analysis procedure, described above, also allows analysis of the distribution of exposure across individuals in a subgroup, and it is then possible to answer the question, "Is the average dietary burden due to a few individuals with a large exposure or is it due to a large number of individuals with a low exposure?" The results of monitoring data, summarized in Section IV of this document were used to assess the potential dietary burden for the U.S. population and for subgroups. The mean dietary burden for the U.S. population from consumption of EDB-contaminated grain is 0.55×10^{-5} mg EDB/KG body weight/day. Generally dietary burdens parallel grain consumption. at is, subgroups, such as 1-6 year olds who had higher grain consumption also had higher dietary burdens of EDB. However, the dietary burden is not directly proportional to grain consumption since different residue levels were estimated for corn, wheat, rice and other grains (Table IV-10). Children (1-6) and hispanics have mean exposures which are greater than the U.S. population (Table V-2).

Fig. V-1 shows the percent of individuals whose dietary burden is currently greater than the levels of EDB shown on the

Fig V-1. Effects of sets of proposed action levels on the percent of individuals who exceed each level of EDB: U.S. POPULATION

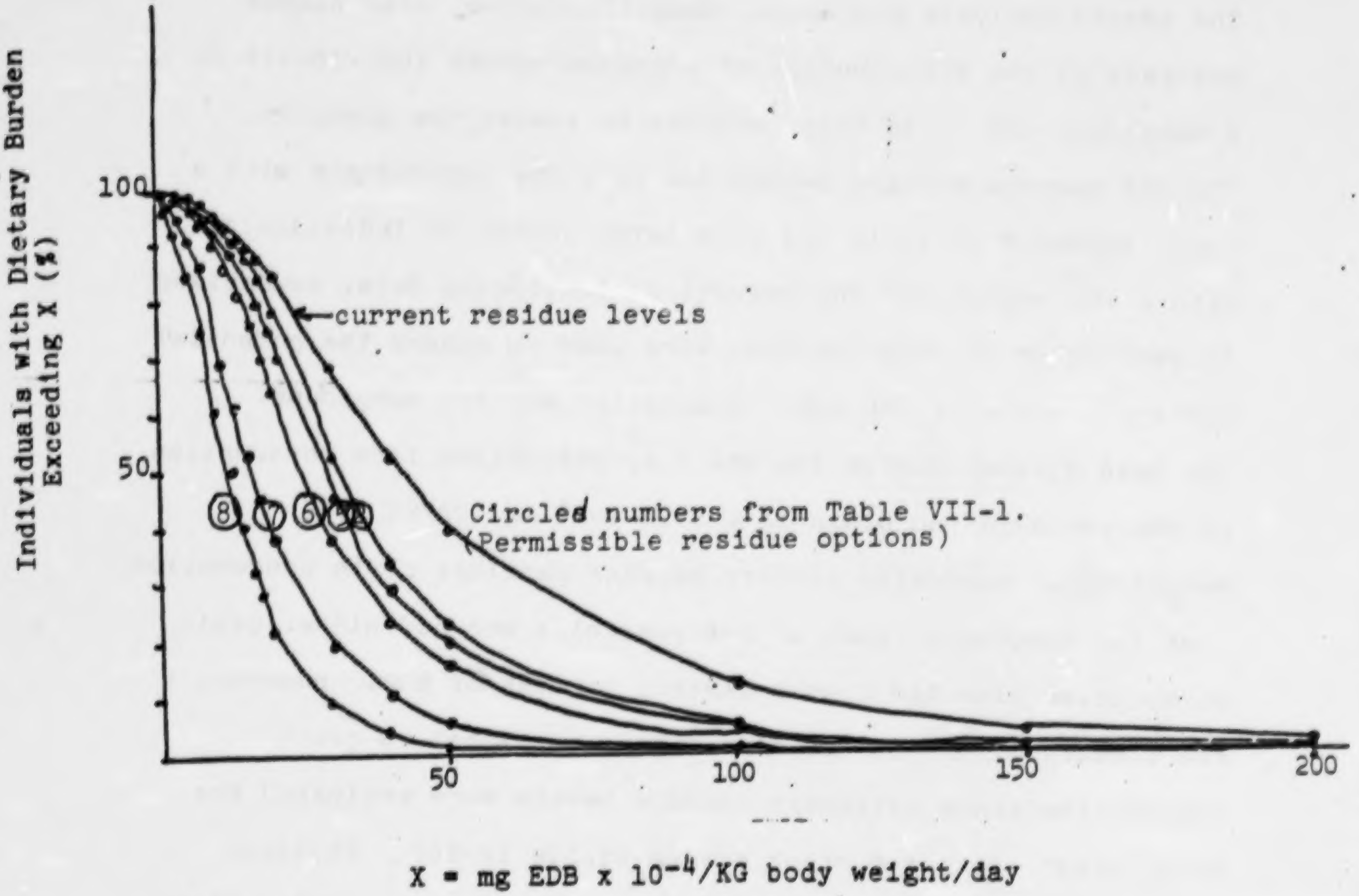


Table V-2. Dietary Burdens for the U.S. population and selected subgroups

	Mean Exposure (mg EDB/kg B.W./day)		DISTRIBTUION (Percent of Individuals in Group exceeding 0.00001 mg/KG B.W./day)b/	
	Current	Under Recommended Action a/	Current	Under Recommended Action a/
U.S. Population	.55x10^{-5}	.34x10^{-5}	12	3
Hispanics	.79x10^{-5}	.43x10^{-5}	25	3
Non-hispanic white	.52x10^{-5}	.34x10^{-5}	11	3
Non-hispanic blacks	.63x10^{-5}	.36x10^{-5}	18	3
Other	.57x10^{-5}	.39x10^{-5}	12	5
Nursing infants	.26x10^{-5}	.19x10^{-5}	5	1
Non-nursing infants	.67x10^{-5}	.45x10^{-5}	23	8
Children(1-6 yr)	1.28x10^{-5}	.77x10^{-5}	62	21
Children(7-12 yr)	.92x10^{-5}	.57x10^{-5}	34	6
Males(13-19 yr)	.63x10^{-5}	.40x10^{-5}	12	1
Females (13-19 yr)	.50x10^{-5}	.31x10^{-5}	5	-
Males(20+ yr)	.42x10^{-5}	.28x10^{-5}	3	-
Females (20+ yr)	.34x10^{-5}	.22x10^{-5}	2	-
Pregnant(13+ yr)	.40x10^{-5}	.25x10^{-5}	3	1
Nursing (13+ yr)	.44x10^{-5}	.30x10^{-5}	4	3
Spring	.53x10^{-5}	.34x10^{-5}	11	3
Summer	.54x10^{-5}	.34x10^{-5}	12	3
Fall	.57x10^{-5}	.36x10^{-5}	13	4
Winter	.56x10^{-5}	.36x10^{-5}	12	3
Northeast	.51x10^{-5}	.35x10^{-5}	10	3
Northcentral	.52x10^{-5}	.35x10^{-5}	11	3
Southern	.59x10^{-5}	.35x10^{-5}	14	3
Western	.52x10^{-5}	.35x10^{-5}	14	3

a/ Recommended action levels of 900 ppb in whole grains, 150 ppb in milled products, and 30 ppb in ready-to-eat products. Calculations assume 100% compliance with recommended levels.

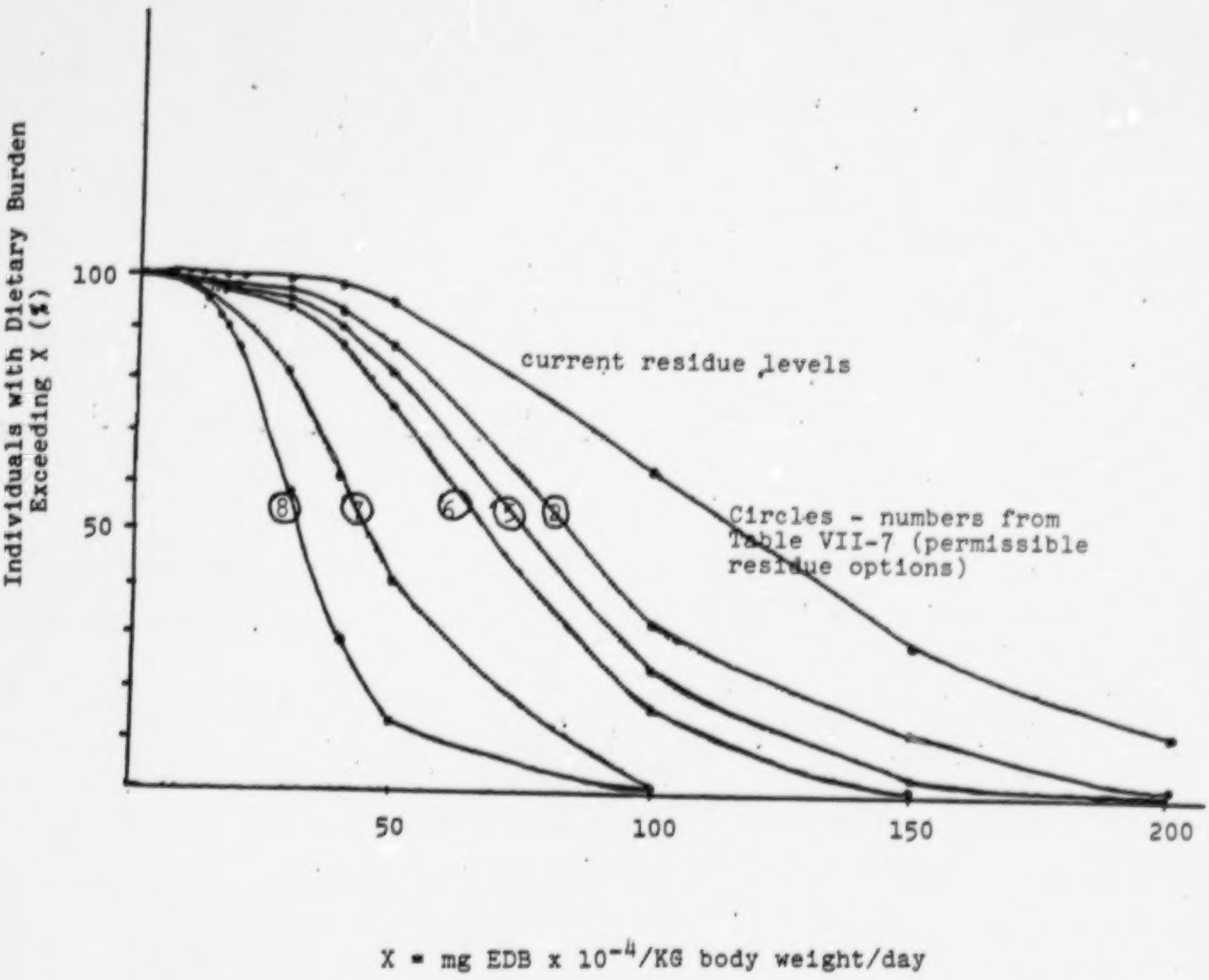
b/ 0.00001 mg/kg B.W./day (approximately 2 times the mean exposure of the U.S. population) was arbitrarily selected as an index value for examining the proportion of individuals in each group with potentially high exposure.

X-axis. Fig. V-1 also shows the distribution of exposure which could be expected to result from 6 possible sets of permissible residue levels. Based on the residue data, currently, 15% of individuals in the U.S. population exceed 0.00001 mg/kg body weight/day. Hispanics have higher exposure with a mean of 0.0000080 mg/kg body weight/day and 29% of the hispanics surveyed exceeded 0.00001 mg/kg body weight; 52% of the hispanics exceeded the U.S. population's average dietary burden. Children (1-6) have a mean dietary burden of 0.000013 mg/kg body weight and 70% exceeded 0.00001 mg/kg body weight; 94% exceed the U.S. population's national average dietary burden. As average EDB consumption levels rise, there is a rapid decline in the percent of individuals with exposures above that EDB level because the general population has relatively uniform exposures - i.e. a large number of individuals with similar consumption patterns. However, it must be noted that each individual was surveyed for only 3 days.

EPA has considered 11 possible sets of permissible residue levels. It is assumed that as a result of regulatory actions, all commodities above these levels would be removed from the food supply and that the average residue level for each type of grain would decline (Table IV-10).

The proposed regulatory action, assuming complete compliance, will lower mean exposure for each population subgroup and the percent of individuals within each subgroup who exceed specified levels of EDB (See Figures V-1, V-2, and Table V-2). In all subgroups, the lower the permissible residue levels, the lower the dietary burden.

FigV-2 Effect of sets of proposed action levels on the percent of individuals who exceed each level of EDB: CHILDREN (1-6 YRS)



C. Summary of Procedures Used to Estimate Risk

The average levels of residues in cooked and uncooked grain products was determined using all available residue data. Estimates of average residue levels were calculated separately for corn, wheat and "other grains". The category "other grains" includes rice, barley, oats, rye, buckwheat and sorghum. In the determination of average residue levels, all samples with nondetectable levels of EDB (less than 1 ppb)were conservatively treated as 0.75 ppb. The mean residue level of each product at the uncooked stage was reduced by a factor of 80% to reflect an assumed reduction in residues during cooking. The average residue for both stages (cooked and uncooked) were then combined to yield an overall average which uses all of the available residue data from both cooked and uncooked samples. In combining this data, the means for cooked and uncooked grains were weighted by the number of samples in each data set. Mean residues estimated for each set of maximum permissible residue levels are summarized in Table IV-10. Average residue levels at each level were determined by deleting from the data set those samples above the level. Samples were not gathered in proportion to their diet. For example, bread, rolls and biscuits represent 30%

and cakes about 10% of the grain consumed by adults (Table V-3), yet sampling was not proportional. Also, the proportion of each of these food eaten by different subgroups varies. For example, ready-to-eat cereals represent from 3-6% of the grain consumed by individuals over the age of 15, but 60% of the grain consumed by infants. Residue has been detected in only 2 (of 86) baby cereals and both positive samples were near the limit of detection (1.5 ppb).

In spite of these observations, the monitoring data was not weighted to account for the nonproportional sampling since there was a wide variation in the residue levels reported within product lines as well as across product types.

The estimated mean levels of EDB for each grain type at each set of maximum permissible residue levels were then entered into the dietary consumption models (described in Chapter V) and an estimate of the daily dietary burden was determined for the U.S. population and for each subgroup.

The estimates of dietary burden were then used in the appropriate equations (Chapter VI) in order to predict risk. Dietary burdens were assumed to be constant over the 2-3 year exposure period for which risk has been estimated.

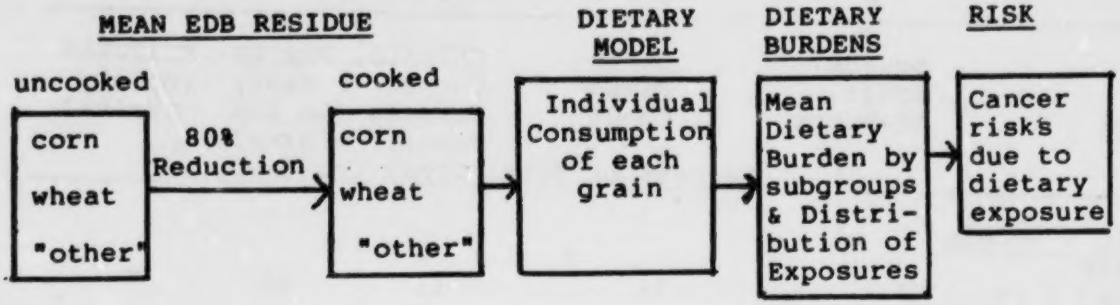
Table V-3. Distribution of consumption among grain products.

Age	Breads, Rolls, Biscuits	Other Baked Goods	CEREALS, PASTAS		MIXTURES (mainly grains)
			Cooked Cereals Pastas	Ready to Eat Cereals a/	
	Percent of Total Grain Consumed				
Male & Female					
Less than 1 yr	10	12	11	60	7
1-2	17	15	19	9	40
3-5	25	20	21	9	25
6-8	26	27	20	9	18
Males					
15-18,	30	25	11	6	27
23-24,	32	23	13	3	29
Females					
15-18	29	22	16	5	28
23-34	30	23	16	4	27

a/ Include dry infant cereals.

Adapted from Table 1.3a, Grain Products, Fats, Oils; (USDA, 1980).

The procedure used to generate risk estimates for children (1-6) and to the U.S. population is summarized below:


MEAN EDB RESIDUE
uncooked
corn
wheat
"other"
80% Reduction
cooked
corn
wheat
"other"
DIETARY MODEL
Individual Consumption of each grain
DIETARY BURDENS
Mean Dietary Burden by subgroups & Distribution of Exposures
RISK
Cancer risks due to dietary exposure

D. Technical Notes

A detailed description follows of the USDA Food Consumption Survey and procedures used to convert that survey to equivalent quantities of raw agricultural commodities.

1. USDA Survey Design.

Briefly, the USDA 48-state sample survey design consisted of three levels of stratification. First, all housing units in the United States (based on the 1970 Census) were grouped according to the nine census divisions. Within each division housing units were then grouped into three zones -- central cities, remaining metropolitan areas, and non-metropolitan counties. A third level of stratification was carried out within each of the 27 Census division/zone combinations. This was accomplished by forming groups containing approximately 600,000 households based on political/economic similarities and geographical proximity. Overall, the three levels of stratification resulted in a total of 114 strata. Each stratum was divided into primary sampling units (PSU) and one PSU was selected from each stratum with probability proportional to size. Each selected PSU was divided into clusters of 100 or more housing units called "area segments". A total of 2550 segments were selected with the number of segments in a PSU being proportional to the size of the stratum in which the PSU was located. The selection probability of an individual segment in a PSU was proportional to the ratio of the number of units in the segment to the total number of units in the PSU. Finally, housing units were selected from area segments with the sampling ratio determined by: the total number of interviews desired; the estimated occupancy rate; the estimated completion rate; and the increase in the number of housing units from 1970 to 1977.

To provide seasonal information, four samples, independently selected from the same set of PSUs, were implemented in consecutive calendar quarters beginning in April 1977. The sampling ratio for each quarterly sample was determined so as to yield approximately 3750 completed household interviews in each quarter.

A subsample of household members was selected to complete a 3-day record (24-hour recall and a 2-day diary) of individual food items consumed. For the Spring survey, every household member was eligible to complete this record. In the remaining three quarterly samples, all persons younger than 19 and one-half of all persons 19 years and older were eligible.

2. EPA's Food Composition Data.

A computer search of the USDA data revealed that 3734 individual food items -- pizza, chocolate cake, etc. -- had been consumed on at least one occasion. Each food item was then examined and a determination made as to the:

(1) raw agricultural commodities (RACs) -- milk, wheat, carrots, etc -- which make up the food item,

(2) percentage of each RAC, by weight, and

(3) form of each RAC "as eaten" (cooked, raw, fried, etc)

(4) water used in cooking is not included in the estimate of the consumption of each RAC, but is retained as a separate entry - that is 100 g of cooked rice, would be coded as 30 g rice and 70 g water.

Information on how the formulations were derived is given in White, et al. (1983). The food composition data was then merged with the USDA food consumption files to estimate each individual's RAC consumption which was then adjusted for that person's self-reported body weight - that is, all consumption is expressed as g RAC per kg body weight/day.

E. References

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USDA, Science and education Admin. Food and nutrient intakes of individuals in 1 day in the U.S., Spring, 1977 (Preliminary Report No. 2).

VI. Cancer Risks

As noted in previous position documents (PD 2/3 and PD 4), the Agency has concluded that EDB is a potent animal oncogen and a likely human oncogen.

At dietary levels of exposure that have been estimated for grain-based products, cancer risk must be of primary concern. Although potential reproductive hazards can result from exposure to EDB, the inhalation dose levels which have been associated with gonadal toxicity are much greater than the observed and estimated dietary levels. Although EDB may pose a risk with respect to heritable mutations, it is not yet possible to quantify this risk.

The evidence supporting the Agency conclusion that EDB is an animal oncogen results from studies conducted in two species and several routes of exposure. The initial studies that triggered the RPAR were the NCI gavage studies (Hazelton, 1978). Both the NCI rat and mouse bioassays showed significant increases in several tumor types. The most common tumor type observed was a gastric carcinoma. By the end of the first year of the test, 90% of low dose male rats were diagnosed as having this malignant tumor.

Other studies, conducted via the inhalation route of administration, also found EDB to be a potent animal oncogen. The Midwest Research Institute under contract to NIOSH found significant increases in the incidence of tumors of the spleen, mammary gland, adrenals and subcutaneous tissues at an exposure level of 20 ppm (Wong, 1979). NCI found EDB to be oncogenic to rats or mice exposed to dose levels of 10 or 40 ppm via inhalation (NCI, 1980). An increased incidence of hemangiosarcomas (a cancer of the circulatory system) was found in both rats and mice. In addition, a highly significant increase in tumors of the respiratory system (nasal cavity tumors in rats and lung tumors in mice) were observed. Finally, a skin painting study (Van Duuren, 1979) found that repeated painting of EDB on the skin of mice induced not only skin tumors but lung tumors as well.

In summary, EDB has shown to be oncogenic in two species (rats and mice) in both sexes and via three routes of administration (gavage, inhalation and skin painting).

Quantitative risk estimates in general contain a great deal of uncertainty because they must extrapolate from laboratory animals to humans and from the very high exposures used in the laboratory studies to the much lower human exposures. The estimates of risk from dietary exposure to EDB require yet another extrapolation--from partial to full lifetime risk—because the exposed animals in the laboratory study did not live for more than about half their normal lifespan. This additional extrapolation step introduces yet more uncertainty into the process. In addition, the only oral studies available administered EDB by gavage rather than through the diet. The use of gavage data required another step [illegible] correct for gavage vs dietary routes, utilizing data from a different chemical.

Much care and effort has been put into the quantitative extrapolation procedure to ensure that all the assumptions and extrapolations are handled in the most appropriate way. Nonetheless, there is unavoidable uncertainty remaining in the estimates and they are appropriately taken as only rough indications of potential risk.

The cancer model used in the PD 4 to extrapolate risk from the NCI bioassays, has been developed by the EPA Carcinogen Assessment Group (CAG). The risk model used in the PD 4 to estimate risks from dietary exposure incorporated a time parameter which allowed the differential risks for less than lifetime exposure for different age groups to be estimated from the data in the oral (gavage) study. This was possible because of the extraordinary rate of unscheduled deaths with tumor which occurred in the study. CAG has concluded that "the model fits the data well, it is consistent with the biological hypothesis of direct acting genotoxic agents and it permits a direct estimate of the effect of partial lifetime exposure to be made."

The model takes the form:

$$P(t,d) = 1-e^{-x}$$

where: $x = (1.02 \times 10^{13}) \times d \times W_m^{1/3} [(t-s)^{7.6}-(t-f)^{7.6}]$

W = average weight of the individual from age f to s (in kg)

s = age at start of exposure (years)

f = age at end of exposure (years)

d = mg/kg/day exposure from age s to f

t = age at end of observation period (years).

For a lifetime exposure, $W_m = 60$ kg., $s = 0$, $f = t = 70$ yrs. of age, and the above equation has the form $p(d) = 1 - e^{41d}$.

Earlier, before the PD 4 model was developed, the Agency used a simpler model which did not utilize this time-to-death-with tumor information. Instead, this model made the simplistic assumption that risks from less-than-lifetime exposures are directly proportional to the length of the exposure, regardless of the age at which exposure occurs. This model takes the form:

$$P(d) = 1-e^{-18.71d}$$

where: d = average mg/kg/day exposure over a 70-year lifespan

Both of these models were used to generate the range of risks in Table VI-1.

Table VI-1. Cancer Risks of Alternative Permissible Residue Options for EDB in Grain Products

Permissible Residue Option		Exposure (Estimated Actual Intake)		Cancer Risk c/ (2 to 3-Years Exposure) d/	
No.	PPB a/	PPB in Grain Diet	Mg/Kg/Day Child. Adult	Child (1 yr.)	Adults (30 yr.)
1	Current Exposure	2.9	1.3×10^{-5} 6×10^{-6}	10^{-6}-10^{-4}	10^{-6}-10^{-5}
2	50/250/ 5,000	2.1	9×10^{-6} 4×10^{-6}	10^{-6}-10^{-4}	10^{-6}
3	30/150/ 3,000	1.8	8×10^{-6} 3×10^{-6}	10^{-6}-10^{-4}	10^{-6}
4	30/150/1,000	1.8	8×10^{-6} 3×10^{-6}	10^{-6}-10^{-4}	10^{-6}
5	30/150/500	1.8	8×10^{-6} 3×10^{-6}	10^{-6}-10^{-4}	10^{-6}
6	20/100/2,000	1.6	7×10^{-6} 3×10^{-6}	10^{-6}-10^{-4}	10^{-7}-10^{-6}
7	10/50/1,000	1.1	5×10^{-6} 2×10^{-6}	10^{-6}-10^{-5}	10^{-7}-10^{-6}
8	5/25/500	.8	3×10^{-6} 2×10^{-6}	10^{-6}-10^{-5}	10^{-7}-10^{-6}
9	1/5/100	.5	2×10^{-6} 9×10^{-7}	10^{-6}-10^{-5}	10^{-7}
10	<1/1/100	<.5	$<2 \times 10^{-6}$ $<9 \times 10^{-7}$	$<10^{-5}$	$<10^{-7}$
11 b/	Sliding scale	1.2 Average	5×10^{-6} 2×10^{-6}	10^{-6}-10^{-4}	10^{-7}-10^{-6}

a/ Permissible residue options listed are for ready-to-eat consumer products, milled products and raw grain respectively. Parallel levels assume a 10-fold increase from the finished product to the uncooked product and a 20-fold increase from uncooked product to grain (with the exceptions of #4, #5, which assume a 6-7-fold increase from uncooked product to grain).

b/ Permissible residue option 11 assumes 6 months enforcement at 20/100/2,000 followed by permanent enforcement of 10/50/1,000 ppb.

c/ Range in cancer risk using dietary cancer models presented in the PD 2/3 and PD 4.

d/ A constant exposure was assumed for calculation purposes. It is predicted that exposure will actually decline after the suspension is in effect.

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VII. Toxicity of Likely Chemical Alternatives

A. Aluminum Phosphide

Aluminum phosphide is formulated as tablets or pellets which liberate highly toxic phosphine gas when the aluminum phosphide reacts with moisture in the commodity or surrounding air. Because of the highly toxic nature of the phosphine which is liberated, formulations of aluminum phosphide have also been considered as highly toxic materials (EPA, 1981).

A two-year rat feeding study examined the effects of feeding diets fumigated with phosphine gas to rats (Hackenberg, 1972). Analytically determined levels of phosphine in the diet ranged from 0.2 ppm to 7.5 ppm and averaged approximately 1 ppm. No differences were found between control animals and those animals receiving treated diet with respect to growth, food consumption, survival, morbidity, hematology, blood chemistry, gross and microscopic pathology.

B. Ethylene Dichloride

Ethylene dichloride (1,2-dichloroethane) has a relatively low toxicity to mammals on an acute basis (LC_{50} = 12,000 ppm. or 48 mg/L for 0.53 hour of exposure). The primary effects of human exposure to ethylene dichloride were reported to be central nervous system (CNS) depression and gastrointestinal upset. Liver, kidney and adrenal injuries occurred in a dose-related fashion.

This chemical is rapidly metabolized and eliminated in mammals. The metabolic pathway of EDC is not adequately delineated, but very likely occurs via a dechlorination reaction. The metabolism of EDC may be catalyzed by the glutathione system in the soluble fraction of the liver. EDC metabolities include monochloroethanol and monochloroacetic acid which are more toxic than EDC.

The chemical was shown to be mutagenic in the reverse mutation assay in Salmonelia typhimurium TA1535 and TA100 with and without metabolic activiation (McCann, 1975). Metabolities of EDC are also known to be mutagenic (McCann, 1975).

There is evidence that exposure to ethylene dichloride poses a carcinogenic risk to man. An NCI study showed statistically significant increase of tumors in both rats and mice after long-term oral intubation (Dhew, 1974). A statistically significant positive association between the dosage and the incidence of squamous cell carinomas of the forestomach and hemangiosarcomas of the circulatory system occurred in male rats but not in females. There was also a significantly increased incidence of adenocarcinomas of the mammary glands in female rats. The incidence of mammary adenocarcinoma in female mice were statistically significant. The EPA Carcinogen Assessment Group concluded that EDC was 50 times less potent as an oncogen than EDB (Albert, 1978).

C. Carbon Tetrachloride

CCl_4 was found to be oncogenic (liver tumors) in rats, mice, and hamsters after oral administration. Other chronic effects observed in laboratory animals included cirrhosis of the liver after oral, subcutaneous, or inhalation exposure of rabbits, rats, mice, and hamsters; severe liver damage observed in humans after chronic exposure; kidney damage in humans and rats (nephrosis and degenerative changes).

Fetotoxic effects have been observed by Schwetz, et al (1974) in rats exposed to CCl_4 vapor. Bhattacharyya (1963) also reported fetal as well as neonatal effects in rats exposed via inhalation. Testicular atrophy and impaired spermatogenesis have also been observed in male rats which were given intraperitoneal doses of CCl_4 (Chatterjee, 1966: and Kalla and Bansal, 1975).

No genotoxic activity has been reported in bacteria (McCann et al, 1975), yeast (Callen et al, 1980), or rat liver cells *in vitro* (Dean and Hudson-Walker, 1979). *In vitro* experiments indicate CCl_4 may also bind to other macromolecules which could be the reason many microbial or *in vitro* assays were negative (Rocchi, 1973, Uehleke, 1976).

D. *Methyl Bromide*

Methyl bromide has not been well studied toxicologically. It is currently being tested for oncogenicity by the Dutch government and the National Toxicology Program. Three *in vitro* mutagenicity studies indicated a mutagenic potential for methyl bromide with mutagenic effects shown in a dose dependent manner. Test systems used were *Salmonella*, the yeast *Saccharomyes cerevisiae* and chinese hamster ovary cells. A 3-generation reproduction study via the inhalation route is being sponsored by several manufacturers of methyl bromide. Teratogenicity studies of methyl bromide (in the rat and mouse) have been submitted to the Agency. Although they have not yet been evaluated, the authors of the study report no teratogenic effect at the highest dose level administered.

E. Carbon Disulfide

Carbon disulfide is a volatile and extremely flamable liquid.

Chronic exposure to carbon disulfide at airborne concentrations greater than 30 mg/m^3 has been associated with diseases of the cardiovascular and nervous system. Acute exposure to carbon disulfide at airborne concentrations greater than 60 mg/m^3 has been associated with physiological and behavioral abnormalities. The chemical was also reported to cause a marked decrease in visual acuity as a result of an effect on the optic nerve (Potts, 1980).

In experimental animals, subchronic exposure to concentrations greater than 50 ppm caused brain weight depression accompanied by histopatholgoical changes in the nervous system in rats. In addition, compound-related renal lesions and pigmentation of the spleen were also reported in mice.

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VIII. Economic Impacts

A. Introduction

The purpose of this section is to provide information on economic impacts and implications of implementation of national maximum permissible residue levels for EDB in grain, flour and related finished or consumer products and economic impacts of emergency suspension of grain fumigation and spot-treatment uses of EDB. Specifically, this section focuses upon alternative sets of maximum residue levels for grain and related products which may contain EDB residues from either treatment of grain or spot-fumigation of milling machinery. Economic impacts of emergency suspension are evaluated for 6 months and for the remainder of the cancellation proceedings already in process. The cancellation hearings are expected to require about two years for completion.

This report is intended to meet the requirements for Regulatory Impact Analysis as established by Executive Order 12291, the Regulatory Flexibility Act and Section 25 of FIFRA. It also serves as an input for preparing any analysis required under the Paperwork Reduction Act of 1980.

Executive Order 12291 requires that adequate information concerning the need for, and consequences of, a proposed action be presented. The Order requires that a finding of potential benefits to society will outweigh the potential cost for any recommended action. Executive Order 12291 also recognizes that legal constraints may play a role in selecting among alternative approaches to achieving regulatory goals. The Regulatory Flexibility Act requires that regulations take special note of the impact of proposed regulations on small entities. The Regulatory Flexibility Act requirements can and should be combined with Executive Order 12291 requirements. FIFRA, Section 25, requires that the Administrator of EPA consider such factors as the effects of regulation on production and prices of agricultural commodities, retail food prices and otherwise on the agricultural economy when issuing regulations affecting pesticides. These three mandates for consideration of economic aspects of pesticide regulatory matters are applicable to the revocation of the present exemption and tolerances governing EDB under the Federal Food, Drug and Cosmetic Act, but not to the emergency suspension, which is not rulemaking.

As noted above, this analysis focuses on alternative options for issuance of maximum permissible levels for EDB in food/feed grain products. The specific options range from less than one part per billion (ppb) to 100 ppb in final consumer products (Table VIII-1). For each option at the final consumer product level (ready-to-eat breads, cereals, etc.), there are corresponding levels identified for processed/uncooked foods (e.g., milled flour) and for raw grain. The alternatives were selected at the final consumer product level to reflect a range of levels which have differing exposure/risk implications for human health. Given those values, the other permissible residue levels for processed/uncooked foods and raw grain were assumed to have fixed relationships with the ready-to-eat products. Obviously, actual levels of EDB residues at the three stages of the marketing system would vary considerably. However, those contained in Table VIII-1 are internally consistent within options and are thought to be reasonable approximations. A separate option for raw grain of 900 ppb was also considered but is not shown in Table VIII-1.

This analysis is not highly quantitative due to the complex nature of the problem and also due to the short time available for preparing this analysis. Quantitative estimates of usage and economic impacts are included whenever possible. However, in many cases only qualitative estimates are presented. The quantitative estimates should best be considered as illustrative of possible economic effects rather than values with any known probability of occurrence.

B. Economic Impacts of Setting Maximum Permissible EDB Levels for Raw Grain

1. Usage of EDB and Other Fumigants

EDB is used as a liquid grain fumigant in mixtures whose major constituents are carbon tetrachloride/carbon disulfide and carbon tetrachloride/ethylene dichloride. These fumigants are used as remedial treatments to control insects in stored grain. EDB is also used in combination with chloroform and carbon disulfide, but the overall volume of this product is small in comparison to the carbon tetrachloride-based

Table VIII-1. Maximum Permissible Levels of EDB in Grain and Related Products

Option	Ready-to-Eat	Prepared/Uncooked	Raw Grain
	PPB		
1	100	500	10,000
2	50	250	5,000
3	30	150	3,000
4	20	100	2,000
5	10	50	1,000
6	5	25	500
7	2	10	200
8	1	5	100
9	<1	1	100
10	20/10	100/50	2,000/1,000

products. An estimated 425,000 gallons of formulated products containing 170,400 pounds of EDB active ingredient were used for insect control in grain storage facilities in 1983 (Table VIII-2). At typical application rates, approximately 202 million bushels of grain stored in 1983 were treated with fumigants containing EDB (Table VIII-2).

The majority of EDB usage in the U.S. is to control stored product insects of wheat. Using an application rate of 2 gal. per 1,000 bu., an estimated 159.4 million bushels of wheat were treated in 1983. This quantity of wheat treated with EDB represents about 5.4 percent (Table VIII-3) of the wheat in storage on October 1, 1983 (USDA, Crop Reporting Board, SRS., 1983. pp. 3). In 1983, approximately 14 million bushels of corn were treated with 42,500 gallons of EDB-containing liquid grain fumigants assuming an application rate of 3 gallons per 1,000 bushels. This amount of corn treated with EDB-containing liquid grain fumigants represents about 0.5 percent of the corn in storage on October 1, 1983. The usage on oats, barley, rye and rice comprised approximately 10 percent of the EDB usage in 1983. Crop-specific data for these commodities are not available, but overall, approximately 21 million bushels were estimated to have been treated in 1983. The remaining usage of EDB was to treat approximately 7 million bushels of grain sorghum, which would equal 1.8 percent of that commodity in storage on October 1, 1983.

While actual usage statistics are not available to indicate the precise locations of EDB usage, it is believed that approximately 65 percent of the annual EDB usage is on farms and the remaining 35 percent used in all off-farm positions. According to Douglas Chemical Co. data, Minnesota, North Dakota, Iowa, South Dakota, Nebraska, Oregon and Indiana were states which received the bulk (60.8 percent) of Douglas' 1983 distribution of EDB containing products (Table VIII-4).

Table VIII-2. Estimated Usage of EDB-Containing Liquid Grain Fumigants by Crop, 1983

Stored Commodity	Percent of EDB Usage	Pounds A.I. Applied	Gallons Applied	Application Rate	Bushels Treated
				(gal/1,000 bu)	(000)
Wheat	75	127,800	318,750	2	159,375
Corn	10	17,040	42,500	3	14,167
Oats, Barley, Rye, Rice	10	17,040	42,500	2	21,250
Grain Sorghum	5	8,520	21,250	3	7,083
Total	100.0	170,400	425,000	N/A	201,875

Source: EPA Estimates; Douglas Chemical Co., 1984.; Harein and Sumner, 1982.

Table VIII-3. Estimated EDB Treated Grain as a Percentage of Grain Stocks On-Farms and All Stock Positions, Various Dates, 1983

Commodity	Bu. Treated		Treated as Percentage of On-Farm Storage	 All Positions
			-Percent-	
Wheat	159,375,000	Jan 1	13.7	6.3
		Apr 1	18.0	8.5
		Jun 1	22.9	10.3
		Oct 1	12.9	5.4
Corn	14,167,000	Jan 1	0.23	0.2
		Apr 1	0.3	0.2
		Jun 1	0.4	0.3
		Oct 1	0.9	0.5
Sorghum	7,023,000	Jan 1	2.6	0.9
		Apr 1	4.7	1.1
		Jun 1	7.4	1.3
		Oct 1	12.0	1.8

Sources: USDA. Grain stocks, October 1983; and Table VIII-2.

Table VIII-4. Distribution of Douglas Chemical Co. Liquid Grain Fumigants Containing EDB by State, 1983

State	Gallons	Percent of Total
MN	55,602	17.8
ND	27,240	8.7
IA	27,098	8.2
SD	25,660	7.7
NE	24,235	7.0
OR	21,996	6.6
IN	20,555	4.8
IL	15,164	4.7
MT	14,859	3.9
AR	12,219	3.7
OH	11,535	2.6
MO	8,141	1.8
CO	5,610	1.6
PA	5,082	1.2
VA	3,635	1.1
GA	3,414	0.9
MI	2,755	0.7
NY	2,312	0.7
WI	2,247	0.6
NC	1,938	0.3
AL	965	0.1
KS	335	0.1
WY	251	0.1
TX	106	<.1
Subtotal	292,954	93.6
Misc. Dealer Sales	20,046	6.4
Total	313,000	100.0

NOTES: Total lbs. of EDB = 78,953 (Douglas products only).
Lbs. of EDB per gal. = 0.252 (Douglas products only).
Estimated total lbs. EDB on all formulations = 170,383.

Source: W.P. Conrath, Vice President, Douglas Chemical Company. January 18, 1984.

According to USDA, the most commonly used fumigation method in small farm-type bins is the application of liquid fumigants in a coarse spray over the grain surface (USDA, 1979). This method relies on gravity to distribute the fumigant down through the grain mass as the heavier-than-air vapors change from the liquid form. Pre-application procedures include leveling the grain surface and sealing the juncture between the sidewall and roof with masking tape. Fumigants are usually applied using a bucket pump or garden sprayer adapted to produce a coarse spray. Fumigants are normally applied from outside the bin. After treatment, the access door and fillhole lid are sealed with masking tape or plastic sheeting to prevent fumigant vapors from escaping to the outside.

2. Profile

Grain production is one of the major agricultural sectors in the U.S. In 1983, a total of 8.281 billion bushels of major grain crops were produced. The total supply (production, beginning inventory and imports) for the 1983/84 crop year was 14.006 billion bushels (Table VIII-5). Several hundred thousand farms are engaged in production of major grain crops. Nearly 900,000 farms , [illegible]uce corn and more than 380,000 produce wheat. Other crops involve fewer farms.

There were a total of more than 1 million grain farms in the U.S. in 1978; 589,480 had sales exceeding $20,000 (U.S. Dept. of Commerce, 1981). While actual data are not available, the average quantity of commodities stored on farms in bulk on January 1, 1980-1982 could range between 7,576 and 13,497 bushels per farm (Table VIII-6). The estimated average storage capacity per farm could range between 10,956 and 19,518 bushels.

Table VIII-5. Economic Profile Information on U.S. Grain Production

Grain	Total Production 1983	Total Supply 1983/84	Stocks 1/1/84	No. Farms (Harvesting) 1978
	- - - - - - - - - - -Mil bushels-		- - - - - - - - - - -	(000)
Wheat	2,425	3,970	2,325	383
Corn	4,121	7,262	4,928	893
Oats	473	715	378	326
Barley	532	765	378	97
Rye	28	35	20	9
Rice	220	378	123	7
Sorghum	482	881	651	115
Total	8,281	14,006	8,803	

Sources: Grain Stocks, USDA, Jan. 23, 1984
Feed Outlook and Situation Report, USDA, Nov., 1983
U.S. Census of Agriculture, 1978, Census Bureau
Automated Data Base, Data Resources, Inc., 1984

Table VIII-6. Estimated Quantity of Commodity Stored on Farms January 1, April 1, June 1, and October 1, 1980-82 Average a/

Stock Position Date	Quantity Stored	Estimated Average Grain Stored Per Farm	
		All Farms b/	Farms with sales >$20,000 c/
		-Bushels-	
January 1	7,956,000	7,576	13,497
April 1	5,242,000	4,992	8,893
June 1	3,575,000	3,404	6,065
October 1	3,071,000	2,924	5,210

a/ Includes corn, sorghum, oats, barley, wheat, rye, flax seed, soybeans, and rice.

b/ Quantity stored divided by the 1,050,178 grain farms in the U.S. (1978 Census of Agriculture). Assumes all farms have equal storage capacity.

c/ Quantity stored divided by the 589,480 grain farms in the U.S. with sales greater than $20,000. Assumes all grain storage capacity is concentrated on larger farms.

Circular steel bins are the most common structures used for on-farm storage. While precise data are not available, it is estimated that steel bins comprise 90-95 percent of long-term on-farm grain storage. There are still some structures built of wood which are generally used for storage of bumper crops. Newer structures (i.e., circular steel bins) usually have aeration systems while older structures (wooden construction) are often not so equipped. Most modern structures can be treated with any of the common grain fumigants. The exception would be crib-type structures.

Off-farm storage includes all forms of grain containers used to hold, handle, or transport grain from the time the grain leaves the farm until it is either sold to processors or is exported. This definition includes, but is not necessarily limited to, country elevators, terminal elevators, port facilities, railroad cars, barges, trucks, and so forth.

There are over 15,000 off-farm grain handling and storage facilities in the U.S. with nearly 7.5 billion bushels of capacity. Commercial facilities in the Corn Belt, Northern and Southern Plains comprise about two-thirds of this capacity. The Lake, Delta and Pacific States comprise an additional 20 percent of capacity. The remaining capacity is nearly uniformly distributed throughout the remaining production regions. January 1 grain storage stocks (1979-81) averaged 4.3 billion bushels or 57 percent of capacity. Corn and wheat dominate grain storage with 43 and 26 percent of total volume, respectively. Soybeans account for an additional 19 percent of total storage volume.

3. Quantities Exceeding Maximum Permissible Residue Levels

A key aspect of evaluating economic impacts of maximum permissible residue levels is estimation of the quantities of grain that would exceed such specified levels. In this case, the quantities have been estimated as a percentage of stocks as of February 1, 1984 that would be used for human food consumption or export. The procedure used was as follows:

a. Adjust 1/1/84 stocks for pro-rata share which would not be used for U.S. human consumption or export, i.e. feed/seed uses. A percentage was estimated to be used for feed/seed and was subtracted from the total 1/1/84 stocks, based upon projected 1982/83 usage (1983/84 not available).

b. Stocks for food/export use as of 1/1/84 were reduced by 8.3 percent to approximate stocks as of 2/1/84, due to assumed dispersal during January, 1984.

c. Grain stocks estimated to exceed maximum permissible levels of EDB were based upon a statistical analysis of grain residues submitted by GMA/states/USDA. This statistical analyses was performed by EPA staff (OPPE).

d. Quantities exceeding maximum permissible levels were computed by multiplying the percentages of grain samples exceeding permissible residue levels by food/export stocks as of 2/1/84.

The results of the estimation process are presented in Tables VIII-7 and VIII-8 for each maximum permissible residue level. The grain stocks estimated to exceed the maximum permissible residue levels ranged from a low of 0.2 percent exceeding 5,000 ppb (9.5 million bushels) to a high of 6.3 percent at 100 ppb (250 million bushels).

4. Impact Analysis

a. Direct Impacts

One of the potential economic impacts from enforcing maximum permisssible residue levels is that grain could be withdrawn from the market. Such withdrawals could be made of grain from storage at the farm level or from storage in commercial channels following marketing from the farm. In this analysis, estimates are made of the aggregate value of bushels that may be lost from such eventualities. The overall aggregate value of all types of grain exceeding permissible residue levels is shown in Table VIII-9. Also, the approximate dollar values of typical sized lots of grain that might be involved are summarized in Table VIII-10. A typical lot of grain at the farm level could range from 6,000 to 13,000 bushels compared with 50,000 to 500,000 bushels or more in commercial channels. (Some shipments of grain are in the millions of bushels.) The value of a 10,000 bushel lot of grain at the farm level ranges from about $17,000 to nearly $40,000 (Table VIII-10). The values for commercial lots of grain would range from about $427,000 for oats to nearly a million dollars for rice.

Table VIII-7. Estimated Quantities of Grain Stocks Available for Food or Export, February 1, 1984

Grain	Stocks 1/1/84	Percent for Food/Export (1983/84)	Stocks 1/1/84 for Food/Export	Stocks Used Jan. 84	Stocks 2/1/84 for Food/ Export
	mil. bu.	pct.	mil. bu.		
Wheat	2,325	87	2,023	169	1,855
Corn	4,928	37	1,823	152	1,671
Oats	378	8	30	3	27
Barley	378	43	163	14	149
Rye	20	15	3	-	3
Rice	123	98	120	10	110
Sorghum	651	30	195	16	179
Total	8,803	50	4,357	364	3,993

Source: See Table VIII-5

Table VIII-8. Quantities of Grain Estimated to Exceed Maximum Permissible Residue Levels for EDB, U.S., February 1, 1984

Permissible Residue Level No.	PPB	Wheat	Corn	Oats	Barley	Rye	Rice	Sorghum	Total
		Percent							
1	None	-	-	-	-	-	-	-	-
2	5,000	0	0.3	0.9	0.9	0.9	0.9	0.9	0.2
3	3,000	0	0.3	0.9	0.9	0.9	0.9	0.9	0.2
4	2,000	0	0.3	0.9	0.9	0.9	0.9	0.9	0.2
5	1,000	0.5	0.3	1.8	1.8	1.8	1.8	1.8	0.6
6	900	0.5	0.7	1.8	1.8	1.8	1.8	1.8	0.7
7	500	1.4	1.4	1.8	1.8	1.8	1.8	1.8	1.4
8	200	NA	NA	NA	NA	NA	NA	NA	NA
9	100	9.2	3.8	3.6	3.6	3.6	3.6	3.6	6.3
10	100	9.2	3.8	3.6	3.6	3.6	3.6	3.6	6.3
11	2,000/1,000	0/.5	.3/.3	.9/1.8	.9/1.8	.9/1.8	.9/1.8	.9/1.8	.2/.6
		Mil. bushels							
1	None	0	0	0	0	0	0	0	0
2	5,000	0	5	0.2	1.3	-	1	2	9.5
3	3,000	0	5	0.2	1.3	-	1	2	9.5
4	2,000	0	5	0.2	1.3	-	1	2	9.5
5	1,000	9	5	0.5	2.6	-	2	3	22.1
6	900	9	12	0.5	2.6	-	2	3	29.1
7	500	26	23	0.5	2.6	-	2	3	57.1
8	200	NA	NA	NA	NA	NA	NA	NA	NA
9	100	171	63	1.0	5.1	0.1	4	6	250.0
10	100	171	63	1.0	5.1	0.1	4	6	250.0
11	2,000/1,000	0/9	3/7	0.1/0.6	0.7/3.2	-	0.5/2.5	1/4	5.3/17.3
Base (food/export stocks 2/1/84)		1,855	1.671	27	149	3	110	179	3,993

Table VIII-9. Value of Grain Exceeding EDB Maximum Permissible Residue Levels, February 1, 1984

Action Level									
No.	PPB	Wheat	Corn	Oats	Barley	Rye	Rice	Sorghum	Total
		million							
1	None	$ 0	$ 0	$ 0	$ 0	$ 0	$ 0	$ 0	$ 0
2	5,000	0	16	0.3	3	-	4	6	26.3
3	3,000	0	16	0.3	3	-	4	6	26,3
4	2,000	0	16	0.3	3	-	4	6	26.3
5	1,000	32	16	0.9	7	-	8	9	72.9
6	900	32	40	0.9	7	-	8	9	96.9
7	500	92	76	0.9	7	-	8	9	192.9
8	200	NA	NA	NA	NA	NA	NA	NA	NA
9	100	602	208	1.7	13	0.3	16	17	858.0
10	100	602	208	1.7	13	0.3	16	17	858.0
11	2,000/1,000	32	16/24	0.2/1.1	2/9	0/0	2/10	4/12	13/86
Price/bushel		$3.52	3.30	1.71	2.57	2.75	3.99	2.85	-

Source: Ag. Prices, USDA, Dec., 1983.

Table VIII-10. Prices and Market Value of Grain, at Farm and Non-Farm Levels, Estimated Average Lot Sizes, November, 1983 Prices

Item	Price/bu. 11/83 a/	Value of Grain/Lot	
		Farm	Non-Farm
Lot size	1,000 bu	10 (6-13)	250 (50-500+)
Wheat	$3.52	$35,200	$880,000
Corn	3.30	33,000	825,000
Barley	2.57	25,700	642,500
Oats	1.71	17,100	427,500
Rye	2.75	27,500	687,500
Rice	3.99	39,900	997,500
Grain Soryhum	2.85	28,500	712,500

a/ Prices received by farmers, Nov. 1983, except for rye, which is preliminary estimate.

Source: USDA: Ag. Prices, Dec. 1983.

These aggregate dollar values and values for a typical lot are obviously very significant if they were to reflect the value of losses to operators at either level in the market as described earlier in this section.

The farmer or other owner of grain with EDB at higher than permissible levels realistically would face a number of options short of losing the entire value of the grain. Such options would include delay of marketing, which would tend to reduce EDB residues due to the natural dissipation of the chemical; turning or moving the grain; and aerating the grain. All of these options have attendant costs of one type or another. Also, the owner of the grain may need to sample and test for residues which would generate additional cost. These types of costs are addressed below in this section of the report.

Turning the grain is one of the methods that farmers and grain merchants may employ to help speed residue dissipation. This turning cost is generally estimated to be between one-fourth and one-half of a cent per bushel with some estimates going as high as one cent per bushel. The major obstacle to overcome when turning grain is breakage. It has been estimated that grain is reduced one grade due to breakage with each turning. For this reason, turning costs for corn would be prohibitive.

As noted above, the owner of grain may wish to have his product analyzed chemically for residues of EDB. Agency staff has recently contacted a number of vendors and found that the cost of analyzing grain or related food products for EDB is approximately $100 to $110 per sample at commercial laboratories. If a large number of samples (i.e., hundreds) are to be analyzed, lower unit cost may be obtained. There are additional costs to be incurred in obtaining and transporting the sample to the laboratory in a manner in which allows for accurate laboratory measurement of actual residues. In instances where statistically valid estimates must be taken of very large lots of grain or a number of lots from a particular geographic area or source, a survey design and random sample must be developed, all of which is an added expense.

Agency staff estimated that approximately 150 to 300 commercial residue chemistry laboratories are available for residue analysis of foodstuffs in the U.S. at the present time. The capacity of these laboratories for EDB testing is not known. If nothing else, there would be a relatively large physical transportation problem in getting all of the samples that could be taken nationwide to the relatively few laboratories nationwide. The extent to which the testing sites might be geographically dispersed has not been evaluated.

The amount of grain required to do chemical residue analysis of grain is likely to be relatively small such as possibly a quart i.e., up to 3 lbs. of grain. The market value of corn is only about 6 or 7 cents a pound and rice. The most expensive grain, about 9 or 10 cents per pound.

b. Indirect Impacts

Implementing EDB residue guidance at the raw grain level in the industry could have indirect effects on other sectors in the economy. Products for which grain is a raw product could be affected as well as substitutes for such products at the intermediate and consumer levels. Also, the livestock sector could be affected if there were significant disruptions in the supply of feedgrains. In view of the relatively small maximum percentages of the grain sector that would be likely to be affected, the potential for such indirect economic effects is quite limited. To the extent they do occur, they would be temporary.

C. Economic Impact of Setting Maximum Permissible EDB Levels for Uncooked Grain Products

1. Usage of EDB and Other Fumigants

This section analyzes the potential economic effects of a range of proposed maximum permissible EDB residue levels for grain-based products which require further cooking. Products included as processed/uncooked are typified by wheat flour, corn-based products, blended and prepared flour mixes (e.g., cake mixes, muffin mixes, etc.) and milled rice. Other product sectors, such as wet corn milling (producing corn starch and corn syrup) and brewing, were not included. Only those industries in the GMA/states/USDA data bases which produce processed/uncooked grain-based products with known residues are considered in this analysis.

EDB finds its way into the human food chain in grain in a variety of ways. As discussed in the previous section, the first route of entry is the direct application to grain stored in bulk. Treated grain goes into the market, becomes mixed with untreated and other treated grain and "disappears" as exports and feed and food components of domestic consumption. The grain containing EDB residues which "disappears" into the domestic diet becomes the initial source of the dietary burden. The second major route of entry is fumigation within the industries which utilize raw grain in milling and processing.

EDB can be used as a spot treatment of cereal processing and flour milling machinery to rid the internal portions of the machines (which are virtually inaccessable) of insect infestations. The major use of the so called "spot" materials containing EDB are wheat and corn-milling facilities. EDB was also used to a very minor extent in a variety of other cereal grain processing industries (e.g., brewing). Virtually every firm utilizing U.S. grain as a feed stock or a basic input item could potentially produce products with detectable EDB residues.

EDB in combination with methyl bromide was the most commonly used fumigant mixture to spot-treat insect infestations in flour milling machinery. Approximately 300,600 pounds of EDB active ingredient were used annually by the flour milling industry (Table VIII-11). While actual data are not available for 1983, the overall usage of EDB for spot-treating flour milling equipment was probably less than typical usage in most recent years. The major companies in the milling industry apparently discontinued usage of EDB in their mills in August and September, 1983. Since that time, the usage of EDB in the milling industry appears to be very limited. Moreover, the largest distributor of spot-fumigant materials (with about 60% of the market) is not a party to the on-going cancellation hearings and registrations for these products are cancelled. Other suppliers are parties to the cancellation hearings, but are no longer producing EDB-containing products for usage in spot-treating milling machinery.

Table VIII-11. Estimated Annual U.S. Usage of EDB as a Spot Fumigant, 1978-1983

Source	Date	Annual U.S. Usage of EDB (pounds a.i.)
Ferguson Fumigants, Inc.	1978	290,000
Research Products Co.	1978	600,000
Millers' National Federation	1978	323,087
Millers' National Federation	1979	323,235
Millers' National Federation	1980	285,759
Environmental Protection Agency	1980	465,000
U.S. Department of Agriculture	1981	162,000
Ferguson Fumigants, Inc.	1981	230,518
Douglas Chemical Co.	1982	164,000
Centaur Associates	1983	300,000
Centaur Associates	1983	300,591

Source: Adapted from Centaur Associates, 1983.

Centaur (1983) estimated that 79 percent of flour mills in the U.S. used EDB as a spot fumigant. Centaur estimated that 231 to 243 flour mills used EDB spot fumigants an average of 10.0 to 10.69 times per year. Respondents to Centaur case studies indicated average usage of EDB-containing fumigants approximated 10.5 gallons per mill fumigation. Obviously, larger mills use more and smaller mills use less. The range in reported usage was 2 to 45 gallons per treatment.

2. Industry Profile

The major raw grain materials for the milling and processing industry include wheat, corn, oats, barley and rice. Of these raw materials, wheat is by far predominant in terms of U.S. consumer importance, and is the most frequently treated with EDB.

The flour milling industry is widely dispersed throughout the U.S. Wheat flour mills tend to be geographically dispersed due to the bulky nature of the input. Transportation costs encourage producers to locate wheat flour mills over a wide geographic range (Table VIII-12). The Corn Belt, Northern Plains and Northeast states comprise over half of total average daily milling capacity. Ownership in the wheat flour milling industry is concentrated in relatively few firms. The leading 5 firms comprise about 72 percent of the wheat flour milling capacity (Table VIII-13).

The production of flour and other grain-mill products from raw grains involves an intricate process of many grindings and siftings. While the details of the entire process will not be given here, in general, about 72 percent of the

Table VIII-12. Daily Milling Capacity of Wheat Flour Mills by Region in the U.S., 1983

Region	Number of Mills	Active Daily Capacity (cwt)	Average Daily Capacity Per Mill (cwt)	Pct. of Total Capacity
Northeast	45	146,962	3,266	13.7
Southeast	12	37,390	3,116	3.5
Appalachian	50	96,691	1,934	9.0
Lake States	20	116,350	5,818	10.9
Corn Belt	37	254,673	6,883	23.8
Northern Plains	26	156,170	6,007	14.6
Delta States	2	11,300	5,650	1.1
Southern Plains	10	69,440	6,944	6.5
Mountain	19	68,450	3,603	6.4
Pacific	18	103,025	5,724	9.6
Puerto Rico	2	9,000	4,500	0.8
Total	241	1,069,451	4,438	100.0

Source: Milling and Baking News. 1983 Milling Directory Buyers' Guide. Kansas City, MO. Sosland Publishing Company, 1982, 120pp. As cited in Centaur Associates, October 13, 1983.

Table VIII-13. Top Ten Wheat-Durum-Rye Milling Companies and Their Daily Capacities

Company	Wheat Flour Capacities (cwt)	No. of Wheat Flour Mills
Con Agra, Inc.	186,300	25
ADM Milling Co.	135,700	17
Cargill, Inc.	130,500	13
The Pillsbury Co.	114,900	8
International Multifoods	60,000	9
General Mills, Inc.	55,000	8
Dixie-Portland Flour Mills	51,000	5
Nabisco Brands, Inc.	43,000	5
General Food Processors, Inc.	31,300	4
Bay State Milling Co.	30,000	5
Total	837,000	99
Total U.S.	1,069,451	241

Source: Milling and Baking News. 1983 Milling Directory Buyers' Guide. Kansas City, MO. Sosland Publishing Company, 1982, 120 pp. As cited in Centaur Associates, October 13, 1983.

wheat kernal is extracted as flour with the remainder as millfeed. The majority of millfeeds are used in a wide variety of animal feeds. The value of flour and other mill products approximated $5.7 billion in 1983 (Table VIII-14).

Flour can be treated in a number of different ways to improve some particular property. Such additives as maturing agents, bleaching agents and self-rising ingredients are blended into the flour at the mill. Other additives such as vitamins and iron are added at the bakery. Blended and prepared flour products were valued at about $1.5 billion in 1983 (Table VIII-14). Two other industry components of this sector are rice milling and wet corn milling. The value of shipments from rice milling and wet-corn milling industries were $1.5 and $4.6 billion, respectively in 1983.

3. Application Practices and Rates

The primary registered uses of EDB as a spot fumigant are in cereal processing equipment, flour elevators, empty flour bins, flour-milling equipment, grain-mill equipment and grain-milling machinery. EDB is particularly effective in flour mills against most common stored product insect pests that infest milling machinery and equipment. There are many ledges and obstructions in milling machinery and equipment that form "dead spots" where product can accumulate. These areas are particularly susceptible to infestation with insects and proper "spot" treatment of these critical locations prevents insect growth and reproduction.

Table VIII-14. Value of Shipments for Selected Industries and Years

Industry	1972	1977	1979	1980	1981	1982	1983 a/
Flour and other grain mill products	2,380	3,683	4,218	4,835	5,103	5,494	5,685
Rice milling	681	1,263	1,397	1,818	1,884	2,040	2,111
Blended and prepared flour	705	1,012	1,172	1,289	1,369	1,460	1,511
Wet corn milling	832	2,015	2,442	3,239	3,378	4,479	4,634
Total	4,598	7,973	9,229	11,181	11,734	13,473	13,941

a/ Estimated.

Source: U.S. Department of Commerce: 1983 U.S. Industrial Outlook. Washington, D.C. 1983. pg. 37-2.

In typical spot fumigation, a 70% EDB and 30% methyl bromide formulation is applied by mill employees or by commercial applicators. The actual application of the EDB product is to only certain parts or "spots" in the milling machinery. Fumigators move from the bottom of the mill to the top of the mill fumigating individual pieces of equipment as they go.

Generally when a mill is fumigated, it is shut down. The milling equipment is allowed to run dry to remove as much grain and flour from the milling machinery as possible. Doors and windows are closed and locked except for the exit door for the fumigators. Typically, the fumigators1/ enter the mill wearing appropriate full-face respirators applying the fumigant to the predetermined spots, working floor-by-floor.

In most cases the applicator uses an application gun, which can be adjusted to allow predetermined amounts of fumigant to be applied. Usually 1 to 4 ounces of EDB-containing fumigant is used per "spot." As each spot is fumigated, the applicator will close up the equipment so that the EDB will volatilize and remain within the equipment for as long as possible.

When the application is complete, a process taking no more than a few hours, the mill is locked and posted with warning signs. The "hold" time within the mill is usually 24 hours, the time needed to kill the insects. Centaur (1983) in case studies indicated that a hold time of 41 hours is common. In several cases, Centaur reported that the applicators complete the fumigation by Saturday noon and the mill remains closed and locked until Monday when it is

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1/ Fumigation is always done by a minimum of two-person teams.

aired out. Some time prior to the resumption of the milling operations, the mill is aerated as much as possible by opening windows and doors and turning on fans and milling equipment blowers. Start-up of mill operations occurs anywhere from zero to several hours after reopening. In Centaur case studies, the average time for reopening to start-up was 3.89 hours, but the range in time varied from zero to 15 hours.

4. Projected Quantities Exceeding Maximum Permissible Residue Levels

The eventual economic impacts of choosing a maximum permissible residue level for EDB in flour will depend on the actual profile of residues existing in flour and grain mill products. A variety of data on EDB residues have been received from GMA, several states, and USDA. It is not known how representative these data may be of actual residues across the nation but for now, these data will be used in analyzing the economic impacts of the proposed permissible residue levels. Quantities of stocks at mills, bakeries and retail outlets with violative residues could not be estimated with available data. The value of stocks potentially violative of each given level were derived using the following methodology and assumptions.

a. All residue data from GMA/states/USDA were assembled into one data base by statisticians in the Agency's Office of Policy, Planning and Evaluation. The percentage of samples of uncooked grain-based products exceeding each level were derived from OPPE printouts.

b. The individual inventory values for wheat, corn, rice and other uncooked grain-based product stocks were not immediately available. The percentages of wheat, corn, and other grain-based products which exceed each permissible residue level, were combined to form a single percentage. This was accomplished by multiplying each percentage that exceeds the level by the food factor coefficients utilized in the Tolerance Assessment System model. The TAS model is the model utilized in determining dietary intake and risks from these intakes elsewhere in the document.

c. About 2/3 of the flour, milled products and blended and prepared mixes are baked within one month of milling. The remaining 1/3 of these products are packaged in consumer-sized units and may remain on retail shelves for an average of 4 months (but usually no longer than 8 months). Milled-rice products were assumed to remain in inventory for 6 months.

5. Economic Impacts

a. Aggregate

Using the asssumptions and data previously discussed, the value of stocks potentially violative were calculated. Table VIII-15 provides the percentage of uncooked products projected to exceed permissible residue levels being considered. For corn and other grain-based products, setting permissible residue levels at 250 ppb or lower could threaten a considerable portion of existing stocks. Only a small portion of wheat products (the major component) would be affected until more restrictive action levels of 50 and 25 ppb are enforced. Because wheat products are dominant, values of products exceeding

Table VIII-15. Estimated Percentage of Samples and Value of Uncooked Products Above Maximum Permissible Residue Level

Option	Maximum Permissible Residue Level (PPB)	Percent of Samples Above Maximum Permissible Residue Level			Weighted Average a/	Value of Products b/ Exceeding Maximum Permissible Residue Level
		Wheat	Corn	Other		
		- - - - - - - -	Percent	- - - - - - - -		- - - - $ million - - - -
1	No Action	N/A	N/A	N/A	N/A	N/A
2	250	0.9	5.6	0	1.2	22.4
3	150	1.6	7.3	0	1.9	35.5
4	100	2.4	7.9	2.2	2.9	54.2
5	50	6.3	11.9	2.2	6.2	115.9
6	25	12.5	15.2	2.2	11.0	205.7
7	10	22.3	23.8	4.3	19.4	362.8
8	5	33.4	36.3	6.5	29.1	544.2
9	1	N/A	N/A	N/A	N/A	N/A
10	50/100	1.6	7.3	0	2.9	54.2

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a/ Samples were weighted using the following food factors: wheat = .73; corn = .1; and other = .17

b/ Based on inventory value of $1.87 billion.

permissible residue levels are relatively nominal at levels 100, 150 and 250 ppb. At 50 ppb, a significant percentage of wheat products were found to exceed this residue level (6.3%). The value of products exceeding 50 ppb approximates $120 million and would be expected to generate signficant economic disruptions. At the 5 ppb permissible residue level, severe economic disruptions are likely for the short term (e.g. 6 months) as the value of stocks exceeding this level is about $540 million.

b. Typical Firm

Although widely dispersed (Table VIII-12), the wheat flour milling industry is dominated by a small number of large companies (Table VIII-13). The top four companies have more than half the daily milling capacity of the industry. For options 1 through 4 (Table VIII-15), producers of corn based products face a much higher probability of having products in violation than wheat or other product manufacturers. The probabilities (measured in percent) for corn and wheat products exceeding maximum permissible residue levels began to converge at the more restrictive levels (50, 25 and 5 ppb). The probability at these levels of having products exceeding permissible levels is about equal for corn and wheat products.

While large firms dominate, the impact of products exceeding any permissible residue level may not accrue in proportion to production capacity. As compared to small firms, large firms may be able to more closely control the source of their grain input and be in a relatively stronger position to produce below-permissible residue-level products. Large firms would also be able to absorb product recall better. At this point, the distribution of the impacts on large and small firms cannot be determined due to the anonymity of the sample origins. Under all but the most restrictive residue levels, few firms would be expected to be seriously affected. Some additional spot sampling of incoming grain for EDB residues by millers can be anticipated at the cost of about $100 per sample. Compared with other overall operational costs, costs at these levels would be considered only incidental.

D. Ready-to-Eat Grain Products

1. Profile

Grain for human consumption reaches the consumer in a variety of forms. Major classes of grain-based food products include cereal breakfast foods, bread and cake products, and cookies and cracker-type products. Table VIII-16 provides recent data on the value of shipments for these groups of food products. After accounting for inflation, these figures still reflect slight real gains in shipments in recent years. Table VIII-17 provides a profile of these same three industry segments.

2. Quantities Exceeding Allowable Levels

Estimation of economic impacts is dependent upon data submitted to the Agency on EDB residues found in ready-to-eat products. Table VIII-18 provides the percentages of products estimated to exceed the alternative residue levels being considered. For those ready-to-eat products for which data on residues are available, setting permissible residue levels as high as 50 ppb would impact on only a small percentage of products in stock. Proceeding to lower and lower permissible residue levels down to [illegible] ppb would place significantly higher and higher portions of ready-to-eat product stocks in situations where regulatory action might be taken.

Table VIII-16. Value of Shipments for Selected Final Grain-Based Products

	Value of Shipments		
Products	1980	1981	1982
	-$ Millions-		
Cereal Breakfast Foods	3,476	3,950	4,298
Bread, Cakes & Related Products	11,703	12,345	13,255
Cookies and Crackers	4,036	4,450	4,700
Total	19,215	20,745	22,253

Source: U.S. Department of Commerce, 1983.

Table VIII-17. Industry Data for Segments of Ready-To-Eat Grain-Based Products Industry

	Cereal Breakfast Foods	Breads, Cakes and Related Products	Cookies and Crackers
No. of establishments	48	3,062	324
No. of establishments with less than 20 employees	13	1,945	152
4 largest firm market share	89%	33%	59%
Employment in thousands	15.4	178.0	45.4

Source: U.S. Department of Commerce, 1983.

Table VIII-18. Percent and Value of Existing Stocks of Ready-To-Eat Grain-Based Products Exceeding Specified Maximum Residue Levels for EDB

Option	Maximum Permissible Level (ppb)	Stocks Exceeding Level	
		Percent	Value ($ mil.)
1	No action	N/A	N/A
2	50	0.1	1.0
3	30	0.9	8.8
4	20	1.5	14.7
5	10	6.1	59.8
6	5	8.7	85.3
7	2	N/A	N/A
8	1	19.2	188.2
9	<1	N/A	N/A
10	20/10 a/	1.5	14.7

a/ Assumes 6 months enforcement at 20 ppb followed by permanent enforcement at 10 ppb.

The immediate initial effect of imposing a maximum permissible residue level would depend on the volume and value of stock in inventory having EDB residues from prior use of EDB as either a grain fumigant or a spot-fumigant for milling equipment. Given the coincident imposition of an emergency suspension of EDB use under FIFRA, the contamination of food products would begin to decline from levels existing prior to the emergency suspension. Hence, the volume and value of contaminated products having residues above a given level would be limited to inventories of products at the time of the emergency suspension and setting of maximum permissible residue levels. Ready-to-eat baked goods have relatively short shelf lives and therefore inventories must reflect this situation.

For bread and cake products, this analysis assumes that inventories would be one week's sales. For other ready-to-eat products, an inventory of four weeks' sales is assumed. Using these factors and the sales from Table VIII-16, the value of inventories of ready-to-eat products are estimated to be about $980 million in 1983 (assumes an inflation rate of 3.47% for grain-based food products in 1983 over 1982). Using the percentages of products exceeding the proposed permissible residue levels, the estimated value of inventories potentially exceeding those levels can be calculated. The results are shown in Table VIII-18. Clearly there could be major economic dislocations depending on the option chosen. In this analysis, the impact would range from less than $1 million to as much as nearly $190 million in value of ready-to-eat products that could be seized for exceeding permissible levels for EDB residues.

3. Economic Impacts

a. Aggregate

The wide range of impacts associated with the alternative permissible residue levels need to be considered in the overall context of the ready-to-eat grain-based product market. At the least strict or highest permissible residue levels, the economic impacts would be relatively small, no more than $10 million in an annual market of over $20 billion. At the more strict or lower levels, the impacts would be significant at nearly $190 million, but the value of commodities affected would still only account for less than 1 percent of annual sales of the affected product classes. The aggregate impacts would likely result in short-term economic dislocations but would not cause long-term industry disruptions.

b. Typical Firm

Referring back to Table VIII-17 which provides information on some aspects of the structure of the segments of the ready-to-eat grain-based industry, it can be concluded that cereal breakfast foods is dominated by a small number of large firms. On the other hand, the bread and cake industry is much more atomistic with a much larger number of small establishments. The cookies and crackers segment fall in between the other two segments.

For several options considered, an individual firm would face a low probability of having products in violation. For those firms that do have such products, the impacts would generally be limited to the amount of product in inventory. Both large and small firms would be potentially affected as there is nothing in these possible actions that is known to favor one group over the other. Individual firms which happen to be small, however, may be affected. The ability of such firms to absorb a recall of its products must be questioned. At this point, it cannot be determined how many small firms might be so adversely impacted as to cause business failure. It can be concluded that under most optional permissible residue levels being considered, that few firms would be expected to be impacted directly and in a highly adverse fashion.

Individual firms could also be affected if they felt it necessary to initiate tests for EDB residues in the raw materials such as flour which they would purchase in the future. Most major firms already use quality control programs with respect to materials used to produce their outputs. The addition of tests for EDB residues would cost an estimated $100 per sample. For firms purchasing inputs in large volumes, the incremental costs would be relatively minor. The cost of residue analysis would be much more significant for firms that purchased materials in smaller lots but feel compelled to test for such residues.

E. Value of All Grain and Related Products Exceeding Maximum Permissible Levels

A summary of the value of all grain and related products that are estimated to exceed maximum permissible residue levels is presented in Table VIII-19. The values range from less than $50 million to near $1.6 billion with the most restrictive option.

Table VIII-19. Value of Grain Products Exceeding EDB Maximum Permissible Levels, by Type of Product, February 1, 1984

Maximum Permissible Residue Level		Raw Grain	Prepared/ Uncooked	Ready-to-Eat	Total
No.	ppb				
		- - - - - - - - - -	- Millions -	- - - - - - - - - -	
1	None	$ 0	$ N/A	$ N/A	N/A
2	50/250/5,000	26	22	1	49
3	30/150/3,000	26	36	9	71
4	20/100/2,000	26	54	15	95
5	10/50/1,000	73	116	60	249
6	5/25/500	193	206	85	484
7	2/10/200	N/A	363	N/A	N/A
8	1/5/100	853	544	188	1,590
9	<1/1/100	858	N/A	N/A	N/A
10	2,000/1,000	13/86	54	15	82/155
11	30/150/900	97	36	9	142

F. Summary of Agricultural and Food Industry Impacts

FIFRA, Section 25, requires that the Administrator of EPA consider the effects of a regulation upon production and prices of agricultural commodities, retail food prices and otherwise on the agricultural economy. In view of the projected aggregate effects from implementing the permissible residue levels being evaluated in the options, there would probably be notable temporary impacts with respect to the affected agricultural commodities if certain of these levels were adopted as enforceable limits. Most growers, grain dealers, milling firms, bakers, food processing companies, and grocery related firms would be affected to some degree. Individuals and firms at each point in the chain from grain production to consumer products may have to absorb losses totalling from less than $50 million to as much as $1.6 billion depending on the residue levels chosen. There would be the possibility of isolated and temporary dissruptions in supplies of raw materials and final consumer commodities. The temporary nature of the disruption, in some instances a matter of a few days, would support the conclusion that overall supply and prices of agricultural commodities would not be severely affected. In general, the dollar-value impacts decline as one moves from the grain storage, through the grain processing sector and finally into the retail sector. In no sector would there be an expectation of any significant permanent structural or behavioral changes.

G. Summary of Small Business Impacts

The Regulatory Flexibility Act requires that agencies issuing regulations take special note of the impacts of proposed regulations on small entities. This analysis has focused upon the owners of grain which could be contaminated by EDB residues, grain milling companies, and processors of consumer ready-to-eat products. The principal groups affected would be farmers, grain storage companies, millers, and bakeries who might have raw materials resulting in EDB residues above permissible levels as finished products. In view of the projected overall aggregate impacts of implementing the permissible residue levels, we conclude that, at certain levels, there is a likelihood of an impact on the significant number of small businesses and farms, many of which would be small entities. The number and profile of those small entities could not be developed in detail with the data available but is suggested in the foregoing analysis.

There is nothing in the proposals which would suggest that impacts would be more likely to occur on small businesses than on larger ones. However, it should be stated that in instances where residues would exceed permissible residue levels and products would be taken from the market, there would be significant economic impacts on those firms. Small firms would be less financially capable of absorbing losses resulting from seizures of their products. Countering arguments can be made that all adverse impacts from this proposal should be temporary and hence firms that can survive the initial impacts would likely remain viable businesses.

H. Economic Impacts of Emergency Suspension

1. Introduction

The Agency has evaluated the economic effects of an emergency suspension of grain and flour milling uses of EDB. Economic impacts were separately evaluated separately for a six-month period allocated for a suspension proceeding and for two years which may be required to conduct the cancellation hearings. The consideration of economic impacts stemming from a suspension is limited to a two-year period because the maximum projected length of a cancellation proceeding would be about two years. A suspension order remains in effect only during a cancellation proceeding. Thus, only the impact which would arise during this period would be at issue in a suspension. Any impacts which would be caused by a suspension, but which would be felt after this period, are also considered.

Economic impacts of suspending grain storage and milling/cereal processing usage of EDB during the six-month period were estimated by assuming all registered alternatives are available. The analysis generally provides qualitative estimates of impacts since data are not available to support precise quantitative estimates.

The Agency's analysis indicates that a six-month and two-year suspension of grain and milling uses of EDB would not significantly affect U.S. production or prices of any commodities or services in relevant sectors. Economic impacts of the suspension would be minor in most cases, even at the local/regional level.

2. Grain Fumigants

a. Usage Profile

Details of the profile of the grain production industry have been presented in Section VIII-B of this report and will not be repeated here.

EDB is used as a liquid grain fumigant in mixtures whose major constitutients are carbon tetrachloride/carbon disulfide (CT/CD) and carbon tetrachloride/ethylene dichloride (CT/EDC). EDB is also used in combination with chloroform and CD, but the overall volume of this product is small in comparison to the CT-based products. An estimated 425,000 gallons of formulated products containing 170,400 pounds of EDB active ingredient were used for insect control in grain storage facilities in 1983. At typical application rates, approximately 202 million bushels of grain stored in 1983 were treated with fumigants containing EDB (See Table VIII-2). During the next 6 months, approximately 25%, or 51 million bushels of grain would normally be treated with liquid grain fumigants containing EDB. This is the approximate quantity that will need treatment with other materials during the next six months if EDB is suspended.

The most likely alternatives to EDB-containing liquid grain fumigant mixtures are the other mixtures of carbon tetrachloride/carbon disulfide and carbon tetrachloride/ethylene dichloride at on-farm storage facilties. At off-farm locations, either the CT/CD or the phosphine producing products would be the major replacements. Both carbon tetrachloride-containing products and the phosphine-producing products are currently in widespread use and available in sufficient supplies to meet grain storage treatment needs during either the six-month or two-year periods.

Treatment costs with alternatives vary depending on many factors. However, the available alternatives can be used at roughly the same (Table VIII-20 and Table VIII-21) or less costs than the EDB-containing materials without any significant loss in insect control. Moreover, the usage of EDB-containing liquid grain fumigants during the first six months of the year comprises only about 25% of annual usage. Thus, the demand for EDB during the six-month emergency suspension period can be met by alternatives.

b. Impact Analysis

If EDB-containing liquid grain fumigants are not available during a six-month suspension period, treatment costs could decline slightly where users shift from EDB to CT/CD containing products. Aggregate costs (assuming all former EDB users shift to CT/CD products) for grain fumigation could decline by $88,000 to $388,000. As for users who choose to utilize the CT/EDC and phosphine products instead of EDB, the cost increases experienced by CT/EDC users could be approximately offset by cost decreases by phosphine users (Table VIII-22).

During a two-year period, treatment costs would decline by approximately $348,000 to $1.5 million if former users of EDB-containing liquid grain fumigants shift to the variety of available CT/CD products. Increased costs that accrue to users who choose to use the CT/EDC product will be offset by those users who can utilize the less costly phosphine producing products.

Table VIII-20. Prices for Selected Grain Fumigants a/, 1983-84

Product	%EDB	Unit	Price Per Unit
			($)
CT/CD/EDB/SO_2	1.2	1 gal	7.95-9.75/gal
Chloroform/EDB	5.0	53 gal	6.45/gal
CT/CD/EDB/SO_2	5.0	1 gal	6.45/gal
		5 gal	7.52/gal
CT/EDB/EDC/SO_2	5.0	53 gal	5.20-6.30/gal
		5 gal	6.16-6.95/gal
		1 gal	6.65/gal
CT/EDC/EDB	7.2	53 gal	5.85/gal
		5 gal	6.50/gal
CT/CD (80-20)	-0-	54 gal	5.30/gal
CT/EDC (30-70)		54 gal	5.15/gal
		5 gal	7.65/gal
CT/CD (85-15)	-0-	53 gal	5.30/gal
		5 gal	5.95/gal
CT/CD/SO_2/Pentane	-0-	53 gal	5.30/gal
		5 gal	5.95/gal
Phosphine	-0-	Flask	40/Flask

a/ EDB = ethylene dibromide
CT = carbon tetrachloride
CD = carbon disulfide
EDC = ethylene dichloride
SO_2 = sulfur dioxide
Phosphine = aluminum phosphide

Sources: J.M. Schultz Seed Company (November 14, 1983), Dieterich, IL.
Pueblo Chemical & Supply Co. (December 5, 1983), Hannibal, MO.
ADI Distributors Inc. (1983). Carmel, IN.
Industrial Fumigant Co. (January 31, 1983). Olathe, KS.

Table VIII-21. Comparative Treatment Costs for EDB and Alternative Liquid Grain Fumigants, 1983-84

Product	Unit	Price Per Gallon	Application Rate a/	Material Cost Per 1,000 Bu.
		($)	(gal./1,000 bu.)	($)
CT/CD/EDB/SO$_2$	5 gal.	6.45	2	12.90
CT/CD/EDB/SO$_2$	1 gal.	7.95-9.75	2	15.90-19.50
CT/EDB/EDC/SO$_2$	5 gal.	6.16-6.95	2	12.32-13.90
CT/EDC/EDB	5 gal.	6.50	2	13.00
CT/CD/ (80-20)	54 gal.	5.30	2	10.60
CT/EDC	5 gal.	7.65	3	23.85
CT/CD (85-15)	5 gal.	5.95	2	11.90
CT/CD/SO$_2$/pentane	5 gal.	5.95	2	11.90
Phosphine	1,000 grams	$40/1,000 grams	150 grams	6.00

Note: Application costs were based on treatment rates for wheat stored in metal bins. Treatment costs for shelled corn and crops stored in wooden bins are higher for all liquid fumigants.

a/ Harein and Sumner, 1982.

Table VIII-22. Estimated Treatment Costs Using EDB Alternatives for 6-Month and 2-Year Periods

Product	Range in Treatment Cost per 1000 bu.	6-Month Treatment Costs a/	2-Year Treatment Costs b/	Change in Treatment Costs with Alternatives: 6 months	Change in Treatment Costs with Alternatives: 2 years
	($)	($ 000)	$ (000)	($ 000)	($ 000)
EDB-containing	12.31-19.50	628-995	4,977-7,878	—	—
CT/CD-containing	10.60-11.90	541-607	4,282-4,808	-88 to -388	-348 to -1,535
CT/EDC-containing	23.85	1,216	9,635	+221 to +588	+1,757 to +4,658
Phosphine	8.00 c/	408	3,232	-220 to -587	-1,745 to -4,646

a/ Assumes treatment of 51 million bushels of grain during the next 6 months.
b/ Assumes treatment of 202,000 bushels annually.
c/ Includes additional labor and materials charge of $2/1,000 bu.

During either the six-month or the two-year time frames, users should not experience any significant changes in the ability to control insects with the CT/CD alternatives.

Overall for either time frame, the comparative costs of using other registered and readily available materials, suggests that users should not experience any s3rious economic impacts if EDB products are not available.

3. Spot Treatment

EDB in combination with methyl bromide has been the most commonly used fumigant mixture to spot-treat for insect infestations in flour milling machinery. There has been a significant decline in the use of the EDB/ methyl bromide mixture as concern has been raised with respect to the safety of these products.

a. Usage/Profile

Details of the usage of EDB and the profile of the grain milling industry have been presented in Section VIII.C.2 of this report. Major findings are that up to 79% of all mills had been using EDB containing products prior to the summer of 1983. Spot treatment of milling equipment has been done on a scheduled basis with treatments being applied about 10 to 11 times per year on average. Flour mills requiring treatment are dispersed throughout the U.S. although there is increased concentration in the Corn Belt, Northern Plains, and Northeast States.

b. Alternatives

Alternative means of insect control in grain milling equipment include the use of other registered pesticides and increased diligence in cleaning and sanitation of the mill machinery. The most likely chemical alternatives to EDB-containing products would be methyl bromide and aluminum phosphide. Other registered products containing ethylene dichloride and carbon tetrachloride could also be used, but these products are less preferred as the larger volume of liquid applied can leave residues that clog the machinery when the mills are restarted following fumigation.

In addition to alternative chemical control measures, millers may need to increase efforts in cleaning machinery. All grain product residues should be removed when machinery is cleaned in order to remove food sources and harborage for insects. The use of improved sanitation practices and the available alternative chemicals will probably increase the labor requirements for insect control in mills.

c. Impact Analysis

Prior to the Agency's cancellation of EDB as a spot-fumigant to treat cereal processing equipment, annual usage of EDB was approximately 300,600 pounds of active ingredient. Major millers stopped using EDB containing fumigants in August/September of 1983, probably intending to await the final outcome of the EDB cancellation hearing. There may currently be usage of EDB by smaller mills, but this usage would have to come from existing stocks as none of the registered producers are currently producing EDB containing products for spot-treating milling machinery. It is estimated that usage has now declined to about 10 percent of its former level. This situation is not likely to change over the next six months since the milling industry no doubt is concerned with the public's concern with respect to the wholesomeness of their products due to EDB residues. Likewise, usage over the next two years would not be expected to be significant.

The milling industry has the option of adopting the use of other registered fumigants and strategies for insect control and apparently has done so since the summer of 1983. Overall, the adoption of these alternative control methods could increase insect control costs by $3.5 - $4.0 million over the next six months and by $15.0 - $16.0 million over the next two years. There remains some uncertainty as to whether the mill will be able to achieve insect control with the alternative chemical that is comparable to control with EDB containing products.

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